QSIT
Validation

The Quality System Inspection Technique (QSIT)

INTRODUCTION

Effective 6/1/97, the Food and Drug Administration (FDA) revised the current Good Manufacturing Practices requirements for medical devices and incorporated them into a Quality System (QS) regulation. With the publication of the QS regulation FDA recognized a total systems approach for regulating medical devices.

The QSIT is a systems type approach to conducting comprehensive inspections of medical device manufacturers.

It was designed and developed by a Center for Devices and Radiological Health (CDRH) sponsored reengineering team, composed of members from CDRH and the Office of Regulatory Affairs, to achieve the following goals and outcomes:

GOALS

G1A **Decrease Time (In-plant):** Decrease the in-plant time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.

G1B **Decrease Time (Total):** Decrease total time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.

G2A **Increase Focus (FDA 483):** Increase the focus of FDA 483 listed Quality System deficiencies on key elements of the major subsystems of the Quality System with linkages to the remaining subsystems.

G2B **Increase Focus (Inspection Approach)**: Increase the focus of the approach to conducting Quality System inspections on the key elements of the major subsystems of the Quality System with linkages to the remaining subsystems.

G3 **Harmonize:** More closely harmonize the inspection technique for conducting Quality System inspections with that used in the international community.

G4 **QS Regulation Coverage:** Provide broad and adequate coverage of the Quality System regulation when conducting a comprehensive Quality System inspection.

OUTCOMES

O1A **Increase Consistency (Among Districts):** Increase consistency among districts for conducting comprehensive Quality System inspections of medical device manufacturers.

O1B **Increase Consistency (Among Investigators):** Increase consistency among investigators for conducting comprehensive Quality System inspections of medical device manufacturers.

O2 **Increase Compliance:** Increase compliance of medical device manufacturers with the Quality System regulation.

O3 **Improve Product Quality:** Improve the quality of medical devices.

O4 **Improve Review Efficiency:** Improve the efficiency of the enforcement action review process.

Concurrent with the development of the QSIT, activities were designed to validate whether or not the QSIT met these goals and outcomes. These activities were scheduled to take place prior to the full-deployment of the QSIT.

A Table of the Activities including the activity champions and numbers and types of activities associated with the goals and outcomes is below.

QSIT VALIDATION ACTIVITY TABLE

		ACTIVITY	
ITEM	GOAL	TEST (test, inspection, study, demonstration etc.)	ANALYSIS
G1	Decrease Time		
A	In-Plant	Layloff/Wells (1)	
B	Total	Layloff/Wells (1-6)	
G2	Increase Focus		
A	FDA 483	Layloff/Wells (1)	
B	Inspection Approach	Layloff/Wells (1,3)	Ruff (2)
G3	Harmonize	Layloff/Wells (1)	Coleman (2)
G4	QS Reg. Coverage		Ruff (1), AdHoc Group (2)
	OUTCOME:		
O1	Increase Consistency		
A	Among Districts	Layloff/Wells (2,3)	Ruff (1)
B	Among Investigators	Layloff/Wells (2,3)	Ruff (1)
O2	Increase Compliance	Layloff/Wells (1,2)	
O3	Improve Product Quality	Layloff/Wells (1)	
O4	Improve Review Efficiency	Niedelman (1), Layloff/Wells (2)	

A variety of the activities involve data generated under actual use conditions during a QSIT Study. During that Study, inspections of medical device manufacturers were conducted using the QSIT. Study demographics are included in this report.

The QSIT validation activities include input from stakeholders such as investigators, compliance officers, regulated industry and international auditing bodies.

Prior to the conduct of each validation activity, a protocol was developed and documented on a QSIT VALIDATION WORKSHEET. After the conduct of the activity, the results were documented on a QSIT VALIDATION ACTIVITY REPORT.

The documentation associated with the pre-deployment validation activities conducted to date follow this introduction.

Dated: 3/18/99

Timothy Wells (CDRH/HFZ-332) and Georgia Layloff (ORA/HFR-SW450)
Validation Sub-team Leaders

G1A

Decrease Time

In-Plant

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
G1A (Activity 1)	Decrease the in-plant time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	The amount of in-plant time to conduct a comprehensive domestic Quality System Inspection
Scope and nature of the process to be followed.[2]	During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct comprehensive medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections and report their QSIT in-plant time per subsystem covered during each inspection on an Evaluation Form. Beginning the week of 1/11/99, the in-plant time for conducting domestic QSIT inspections will be tabulated using data extracted from the Evaluation Forms. This time will be compared to the calculated average in-plan time for conducting comprehensive domestic Quality System inspections using the current approach. Overall responsibility for this activity: T. Wells (HFZ-332) and G. Layloff (HFR-SW450)	
Acceptance criteria (if known)	Decrease of in-plant inspectional time.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**		This activity will provide a direct and objective measurement of the in-plant inspectional time using the QSIT. This activity will also provide an objective comparison of in-plant inspectional time using the QSIT versus the current approach. The objective comparison will be limited by the need to calculate the average in-plant time for conducting an inspection usin the current approach.
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.		This pre-deployment activity objectively measures the satisfaction of the stated goal.

Rev.12/18/98

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
G1A	Decrease the in-plant time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
1	Test	The amount of in-plant time to conduct a comprehensive domestic Quality System Inspection.
Acceptance Criteria	Decrease of in-plant inspectional time.	
Summary of Results	The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. A total of 42 inspections were conducted during the Study. Each investigator reported their QSIT in-plant time per subsystem covered during each inspection on an Evaluation Form. A tabulation of their reported in-plant times is attached. Average in-plant times for the subsystems were: *Note: 1 day = 6 hours* Management Controls 4.2 hours (0.7 days) Design Controls 5.2 hours (0.9 days) CAPA 10.7 hours (1.8 days) PAPC 8.1 hours (1.3 days) The average total in-plant time was 28.2 hours (4.7 days). The calculated in-plant times for domestic inspections conducted using the non-QSIT approach were: 67.1 hours (11.2 days) (Using PODS baseline data for PACs 82830C and 82830D) 56.9 hours (9.5 days) (Using PODS baseline data for PAC 82830C only) This equates to a 58% reduction (Using PODS baseline data for PACs 82830C and 82830D) or 50.4% reduction (Using PODS baseline data for PAC 82830C only) of in-plant inspection time when using the QSIT for conducting comprehensive inspections of domestic medical device manufacturers.	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments	The QSIT instructs investigators to conduct a pre-inspection record review. Records are requested during the preannouncement and are provided voluntarily by the firm. As documented in QSIT Validation G1B (Activity 5) 38 of the 42 QSIT Study inspections were pre-announced. Of those 38 firms, only 30 provided records for review. In addition, investigators reported that on 2 occasions there was not enough time to conduct a pre-inspection review of the provided records. This yields pre-inspection record reviews taking	

	place, at best, for 28 (66.7%) of the 42 inspections. When reviews were conducted, the average time expended was 4 hours. Since record review took place at best only 66.7% of the time, the overall average time expended to review records was 2.7 hours. This time should be considered when comparing the QSIT vs non-QSIT in-plant inspection times. If considered, the total time to evaluate the subsystems (in-plant and pre-inspection record review) was 30.9 hours. This then equates to a 53.9% reduction (Using PODS baseline data for PACs 82830C and 82830D) or 45.7% reduction (Using PODS baseline data for PAC 82830C only) of in-plant inspection time.
Activity Champion(s)	Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332)

Item # G1A (Activity 1)

As documented in QSIT Validation Activities G4, and O1A/B, use of the QSIT results in a comprehensive Quality System inspection of a medical device manufacturer.

During the QSIT Study a total of 42 inspections were conducted. As part of the QSIT Study, investigators reported their QSIT in-plant time per subsystem for each inspection on an Evaluation Form. The data are tabulated in Attachment 1.

The average in-plant time for conducting a QSIT inspection was determined to be 28.2 hours. Defining a "day" as 6 hours, this equates to 4.7 inspection days in the plant.

Since the G1A goal is expressed in terms of a **decrease** in the in-plant time for conducting comprehensive domestic Quality System inspections, the in-plant QSIT inspection time must be compared to the in-plant time spent when conducting a comprehensive inspection using the current approach.

The PODS time reporting system for investigators tracks total inspection time, it does not track in-plant inspection time. Therefore, for the purpose of making a comparison to determine if indeed there was a decrease of in-plant time, the following formula was used to calculate in in-plant time spent when conducting inspections using the current approach.

Total inspection time is made up of three elements: Preparation Time, In-plant Time and Report Write-up Time.

$$P + I + W = T$$

PODS does not track Preparation Time. However, based on the inspectional experience of QSIT Team investigators, the average Preparation Time was estimated to be 8 hours.

$$8 + I + W = T$$

PODS does not track Report Write-up time. However, per the Investigator EPMS element #2 (Fully Successful), that was in effect in FY98, "Write up time does not exceed 35 percent of on-site inspection time, without justification." For this formula the maximum allowable, without justification, write up time of 35 percent will be used.

$$8 + I + .35\ I = T$$

As previously stated, total inspection time is tracked in PODS. Time is tracked per type of inspection performed. For several years, and in accordance with the Compliance Program 7382.830 directive, investigators performing comprehensive domestic medical device inspections reported their time only using PAC 82830C.

With the 6/1/97 implementation of the design control requirements and the new Quality System regulation, investigators were directed per a 5/2/97 email from ORO (D. Dion) to report domestic inspectional time covering design controls under the separate PAC 82830D. This directive was reinforced by HFZ-305 (W. Morganstern/M. Hoban) in the 7/24/97 Monthly Conference Call for Medical Device Investigators. Additionally, the FY 98 workplan directed,

"Design control requirements should be evaluated and reported on the Design Control Inspectional Strategy Report. Report all time used for evaluating design controls and completing the report against PAC 82830D."

The Compliance Program 7382.830 remains as a draft document, and has not been updated to reflect the new 82830D PAC. However, effective 6/1/97, the total time to conduct a comprehensive domestic medical device inspection became a combination of the time reported under PAC 82830C and the time reported under PAC 82830D.

Per an 11/25/98 POVAC data run, covering the period 10/1/97 – 9/30/98, the accomplished time per operation was reported as: PAC 82830C 84.8 hours; PAC 82830D 13.8 hours. This totals 98.6 hours and reflects the time spent to conduct a comprehensive domestic medical device inspection including design controls.

If the assumptions made on preparation and write-up are accurate, then the following calculation can be made:

$$8 + I + .35I = 98.6$$
$$1.35I = 90.6$$

$$I = 67.1$$

Defining a "day" as 6 hours, this equates to 11.2 inspection days in the plant.

If a calculation of in-plant time were made using only the PAC 82830C time of 84.8 hours, the in-plant time would be 56.9 hours (9.5 days).

Depending on which PODS data are used to establish a baseline, either 67.1 hours (11.2 days) or 56.9 hours (9.5 days) are best estimates for in-plant time using the non-QSIT approach.

As reported above, the in-plant time using the QSIT approach was 28.2 hours (4.7 days).

> *Note: The QSIT instructs investigators to conduct a pre-inspection record review. Records are requested during the preannouncement and are provided voluntarily by the firm. As documented in QSIT Validation G1B (Activity 5) 38 of the 42 QSIT Study inspections were pre-announced. Of those 38 firms, only 30 provided records for review. In addition, investigators reported that on 2 occasions there was not enough time to conduct a pre-inspection review of the provided records. This yields pre-inspection record reviews taking place, at best, for 28 (66.7%) of the 42 inspections. When reviews were conducted, the average time expended was 4 hours. Since record review took place at best only 66.7% of the time, the overall average time expended to review records was 2.7 hours. This time should be considered when comparing the QSIT vs non-QSIT in-plant inspection times.*

Attachment 1 - Item # G1A (Activity 1)

IN-PLANT INSPECTION TIME
(Hours)

Inspection Code	Management Controls	Design Controls	CAPA	PAPC	Total
1A1	6	6	6	6	24
1A2	3	6	9	3	21
1A3	3	6	6	3	18
1A4	3	0	6	6	15
1B1	10	0	30	20	60
1B2	6	0	8	10	24
1B3	4	0	10	10	24
1C1	9	7	15	9	40
1C2	4	2	5	5	16
1C3	9	4	15	17	45
1C4	9	12	15	13	49
1D1	3	4	20	5	32
1D2	4	8	20	11	43
1D3	2	2	3	9	16
1D4	4	10	18	7	39
2A1	4	0	10	8	22
2B1	3	12	19	7	41
2B2	5	18	35	4	62
2B3	5	10	11	8	34
2C1	4	0	8	12	24
2C2	4	12	12	12	40
2C3	2	7	10	10	29
2C4	3	8	10	8	29
2D1	4	4	6	4	18
2D2	4	6	8	8	26
2D3	2	4	4	4	14
2D4	4	0	7	7	18
3A1	4	12	12	6	34
3A2	2.5	1.5	5	6	15
3A3	4	10	12	16	42
3A4	3	6	8	5	22
3B1	3	1	5	13	22
3B2	5	6	16	10	37
3B3	4	6	17	13	40
3B4	2.5	4	11	5	22.5
3C1	1	6	6	8	21
3C2	3	1	6	8	18
3C3	2	1	6	4	13
3C4	2	4	5	5	16
3D1	8	5	8	8	29
3D2	2	.5	3	4	9.5
3D3	6	5	5	4	20
Total Time	175	217	451	341	1184
Avg. Time	4.2	5.2	10.7	8.1	28.2
Avg. Days (1 day = 6 hours)	.7	.9	1.8	1.3	4.7

G1B

Decrease Time

Total

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
G1B (Activity 1)	Decrease total time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	Total amount of time to conduct a comprehensive domestic Quality System Inspection
Scope and nature of the process to be followed.[2]	During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct comprehensive medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections and report their QSIT related time per inspection on a CGCS (Form FDA 481A). Participating districts are to submit copies of the CGCSs to HFZ-332. Also, during the period 10/1/98 - 12/31/98, QSIT investigators from LOS-DO may be participating in a TURBO EIR pilot to evaluate the use of a computer program in streamlining the preparation of FDA 483s an EIRs. Beginning the week of 1/11/99, the average time for conducting domestic QSIT inspections will be calculate using PODs data extracted from the submitted CGCSs. Because the use of TURBO EIR may impact on the total inspectional time, LOS-DO inspections involving the use of TURBO EIR will not be included in this calculation. The average time for conducting QSIT inspections will be compared to the average time* for conducting comprehensive domestic Quality System inspections using the current approach. Overall responsibility for this activity: T. Wells (HFZ-332) and G. Layloff (HFR-SW450) *Note: The average PODs reported time for conducting an inspection of a domestic medical device manufacturer using the current approach includes coverage of the Quality System Regulation as well as the Medical Device Tracking Regulation. It will therefore be necessary to factor out the average time spent covering the Tracking Regulation. This will yield the average inspectional time for conducting a comprehensive domestic Quality System inspection using the current approach. The average time spent covering the Tracking Regulation will be determined by querying Device investigators as to the time spent covering Tracking on non-QSIT inspections and also through query of HFZ-305.	
Acceptance criteria (if known)	Decrease of total inspectional time.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**	This activity will provide a direct and objective measurement of the total inspectional time using the QSIT. This activity will also provide an objective comparison of total inspectional time using the QSIT versus the current approach. The objective compariso will be limited by the need to adjust the average POD reported time for conducting an inspection using the current approach in order to factor out the time that is included for covering the Tracking Regulation.	
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.	This pre-deployment activity objectively measures th satisfaction of the stated goal.	

Rev.12/18/98

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
G1B	Decrease total time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
1	Test	Total amount of time to conduct a comprehensive domestic Quality System Inspection.
Acceptance Criteria	Decrease of total inspectional time.	
Summary of Results	The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. A total of 42 inspections were conducted during the Study. Of those 42 inspections, 34 involved non-TURBO EIRs. Investigators reported their QSIT inspection time for each inspection on a CGCS. A tabulations of the reported times for the 34 non-TURBO inspections and also for the 42 total inspections are attached. The average time for conducting a QSIT inspection, based on the 34 non-TURBO inspections was determined to be 56.9 hours. The average time for conducting a QSIT inspection, based on the 42 total inspections, was 55.2 hours. The average time for conducting a non-QSIT comprehensive inspection including design controls is 98.6 hours (Using PODS baseline data for PACs 82830C and 82830D). The average time for conducting a non-QSIT comprehensive inspection is 84.8 hours (Using PODS baseline data for PAC 82830C only) This equates to a 42.3% reduction (Using PODS baseline data for PACs 82830C and 82830D) or 32.9% reduction (Using PODS baseline data for PAC 82830C only) of total inspection time when using the QSIT for conducting comprehensive inspections of domestic medical device manufacturers and involving non-TURBO EIRs. This equates to a 44.0% reduction (Using PODS baseline data for PACs 82830C and 82830D) or 34.9% reduction (Using PODS baseline data for PAC 82830C only) of total inspection time when using the QSIT for conducting comprehensive inspections of domestic medical device manufacturers and involving the total 42 Study inspections.	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments		
Activity Champion(s)	Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332)	

Item # G1B (Activity 1)

As documented in QSIT Validation Activities G4, and O1A/B, use of the QSIT results in a comprehensive Quality System inspection of a medical device manufacturer.

During the QSIT Study a total of 42 inspections were conducted. Of those 42 inspections, 34 involved non-TURBO EIRs. As part of the QSIT Study, investigators reported their QSIT time for each inspection on a CGCS. The data are tabulated in Attachment 1 for the 34 non-TURBO inspections and also for the 42 total inspections.

The average time for conducting a QSIT inspection, based on the 34 non-TURBO inspections, was determined to be 56.9 hours.

The average time for conducting a QSIT inspection, based on the 42 total inspections, was 55.2 hours.

Since the G1B goal is expressed in terms of a **decrease** in the total time for conducting comprehensive domestic Quality System inspections, the total QSIT inspection time must be compared to the total time spent when conducting a comprehensive inspection using the current approach.

The PODS time reporting system for investigators tracks total inspection time. Time is tracked per type of inspection performed. For several years, and in accordance with the Compliance Program 7382.830 directive, investigators performing comprehensive domestic medical device inspections reported their time only using PAC 82830C.

With the 6/1/97 implementation of the design control requirements and the new Quality System regulation, investigators were directed per a 5/2/97 email from ORO (D. Dion) to report domestic inspectional time covering design controls under the separate PAC 82830D. This directive was reinforced by HFZ-305 (W. Morganstern/M. Hoban) in the 7/24/97 Monthly Conference Call for Medical Device Investigators. Additionally, the FY 98 workplan directed, "Design control requirements should be evaluated and reported on the Design Control Inspectional Strategy Report. Report all time used for evaluating design controls and completing the report against PAC 82830D."

The Compliance Program 7382.830 remains as a draft document, and has not been updated to reflect the new 82830D PAC. However, effective 6/1/97, the total time to conduct a comprehensive domestic medical device inspection became a combination of the time reported under PAC 82830C and the time reported under PAC 82830D.

Per an 11/25/98 POVAC data run, covering the period 10/1/97 – 9/30/98, the accomplished time per operation was reported as: PAC 82830C 84.8 hours; PAC 82830D 13.8 hours. This totals 98.6 hours and reflects the time spent to conduct a comprehensive domestic medical device inspection including design controls.

The PAC 82830C time also includes the time spent covering the Tracking Regulation. Based on a 12/18/98 email response to a 12/17/98 email query of HFZ-305, discussions with QSIT Team investigators, the limited number of firms subject to the Tracking Regulation and the limited coverage during inspections, the average time spent covering the Tracking Regulation per total comprehensive inspections conducted annually was estimated to be less then 1 hour per inspection. Therefore, it was not necessary to factor out any time from the above 84.8 hours (PAC 82830C).

TOTAL QSIT INSPECTION TIME
(Non-TURBO EIRs)

Inspection Code	Hours	Inspection Code	Hours	Inspection Code	Hours
1A1	80	2A1	33	3A1	36
1A2	80	2B1	63	3A2	27.5
1A3	130	2B2	107	3A4	35
1A4	82	2B3	60	3B1	40
1B1	70	2C1	32	3B2	55
1B2	40	2C2	40	3C1	31
1B3	40	2C3	47	3C2	48
1C1	95	2C4	28		
1C2	46	2D1	30		
1C3	95	2D2	72		
1C4	96	2D3	68		
1D1	53	2D4	44		
1D2	61				
1D3	22				
1D4	49				
Total Time	1039		624		272.5
Avg. Time per District	69.3		52		38.9

Total # of inspections (Non-TURBO EIRs) 34
Average QSIT Inspection Time per inspection 56.9 hours

TOTAL QSIT INSPECTION TIME
(Including TURBO EIRs)

Inspection Code	Hours	Inspection Code	Hours	Inspection Code	Hours
1A1	80	2A1	33	3A1	36
1A2	80	2B1	63	3A2	27.5
1A3	130	2B2	107	3A3	56
1A4	82	2B3	60	3A4	35
1B1	70	2C1	32	3B1	40
1B2	40	2C2	40	3B2	55
1B3	40	2C3	47	3B3	88
1C1	95	2C4	28	3B4	60
1C2	46	2D1	30	3C1	31
1C3	95	2D2	72	3C2	48
1C4	96	2D3	68	3C3	40
1D1	53	2D4	44	3C4	38
1D2	61			3D1	28
1D3	22			3D2	24
1D4	49			3D3	50
Total Time	1039		624		656.5
Avg. Time per District	69.3		52		43.8

Total # of inspections (Non-TURBO EIRs) 42
Average QSIT Inspection Time per inspection 55.2 hours

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
G1B (Activity 2)	Decrease total time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	Industry responses to a multi-part question on a Custome Satisfaction Survey
Scope and nature of the process to be followed.[2]	During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections. The most responsible person at each of the inspected firms who was directly involved in the inspection will l mailed an OMB approved Customer Satisfaction Survey. They will be invited to voluntarily provide their views on the QSIT by completing and returning the survey form. The survey form will contain the multi-part question, "Did use of the QSIT result in a more efficient inspection by FDA? Yes [ ] No [ ] If yes, how did this efficiency prove beneficial to your firm? Please give examples." Responses will be tabulated and analyzed. Overall responsibility for this activity: G. Layloff (HFR-SW450) and T. Wells (HFZ-332)	
Acceptance criteria (if known)	The majority of survey responses affirm that use of the QSIT resulted in a more efficient inspection by FDA	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**	This activity provides a direct measurement on wheth use of the QSIT approach resulted in a more efficient inspection. A more efficient inspection correlates with decrease in inspectional time.	
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.	This pre-deployment activity allows firms (stakeholders) to provide input into the assessment of this goal.	

Rev.12/18/98

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
G1B	Decrease total time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
2	Test	Industry responses to a multi-part question on a Customer Satisfaction Survey
Acceptance Criteria	The majority of survey responses affirm that the use of the QSIT resulted in a more efficient inspection by FDA.	
Summary of Results	The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. A total of 42 inspections were conducted during the Study. Subsequent to the conclusion of the inspection, the most responsible person at each of the 42 inspected firms who was directly involved in the inspection was mailed an OMB approved Customer Satisfaction Survey. They were invited to voluntarily provide their views on the QSIT by completing and returning the survey form. The survey form contained the multi-part question: "Did use of the QSIT result in a more efficient inspection by FDA? Yes [ ] No [ ] If yes, how did this efficiency prove beneficial to your firm? Please give examples." A total of 19 (45%) industry responses were received. A tabulation of individual responses is attached. Responses to the question were as follows: Yes 16 (84%) No 1 (5%) Other 2 (11%) *(1 response was – both Yes and No, 1 response did not provide a specific yes or no answer.)*	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments		
Activity Champion(s)	Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332)	

Item # G1B (Activity 2)

QUALITY SYSTEM INSPECTION TECHNIQUE (QSIT) CUSTOMER SATISFACTION SURVEY question:

Did use of the QSIT result in a more efficient inspection by FDA? Yes [ ] No [ ]
If yes, how did this efficiency prove beneficial to your firm? Please give examples.

TABULATION of RESPONSES

Form	Yes	No	Other	Comment
1	X			Being able to sample certain Quality records reduced the time needed to assess effectiveness of our major systems.
2			No response	Don't know.
3	X			Allowed to focus on limited number of areas. Did not require excessive amount of time away from day to day activities.
4			Yes and No	The QSIT was intended to be completed within one week because of the key elements. This inspection covered nine working days and 32 calendar days. The longer period of calendar days did allow our facility to respond to some 483 observations which resulted in being able to annotate the 483 with "corrected and verified" – this was beneficial to the facility.
5	X			It tied up fewer employees and took less time to cover the inspector's agenda.
6	X			QSIT resulted in the investigator spending far fewer hours in our plant. This results in less disruption to our operation.
7	X			Inspection was focused and specific to each point of the quality system.
8	X			The inspection was limited to only few days instead of the whole week.
9	X			Kept audit very directed and focused.
10	X			It allowed us to be prepared with documents that we expected the investigator to review, so less time was wasted waiting for copies of the system-level documents.
11	X			Less time required. Specific points targeted – Better representation of our quality system.
12	X			We spent less time in the audit procedure by light reviews of areas we had strengths in and emphasizing our weaknesses.
13	X			Followed questionnaires & we were prepared to answer them.
14	X			Allowed us to commit specific resources for a predictable period of time.
15	X			In just a few days – I knew what work I needed to do.
16		X		As stated in the response to #2, the inspection was very thorough and the QSIT process neither enhanced nor hindered the inspection.
17	X			Scheduling key personnel to be available and in giving us a broader view of our compliance.
18	X			Because the inspection focus was well matched with our implementation the inspection went faster.
19	X			This approach seemed to help the inspector stay on track, covering more material in a comprehensive manner.
TOTAL	16	1	2	

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
G1B (Activity 3)	Decrease total time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	Industry responses to a multi-part question on a Customer Satisfaction Survey
Scope and nature of the process to be followed.[2]	In order to facilitate the inspection, the QSIT directs the investigator, during the preannouncement of the inspection, to request copies of the firm's Quality Policy and high level Quality System Procedures (including management Review Procedures), Quality Manual, Quality Plan or equivalent documents to preview prior to the inspection. Such facilitation will lead towards a decrease in the total time for conducting inspections. During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections. The most responsible person at each of the inspected firms who was directly involved in the inspection will b mailed an OMB approved Customer Satisfaction Survey. They will be invited to voluntarily provide their views on the QSIT by completing and returning the survey form. The survey form will contain the multi-part question, " Did your company receive advance notification of th inspection? Yes [ ] No [ ] If yes, were copies of records voluntarily provided to the investigator by your firm prior to the initiation of the inspection? Yes [ ] No [ ] If yes, which records were voluntarily provided? Did providing such records facilitate the inspection process? Yes [ ] No [ ] Please explain. ____ ..." Responses will be tabulated and analyzed. Overall responsibility for this activity: G. Layloff (HFR-SW450) and T. Wells (HFZ-332)	
Acceptance criteria (if known)	The majority of survey responses from firms which voluntarily provided records affirm that providing such records facilitated the inspection process.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**		This activity provides a direct measurement on whethe providing records prior to the initiation of the inspecti facilitated the inspection process. Such facilitation correlates with a decrease in inspectional time.
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.		This pre-deployment activity allows firms (stakeholders) to provide input into the assessment of this goal.

Rev.12/18/98

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
G1B	Decrease total time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
3	Test	Industry responses to a multi-part question on a Customer Satisfaction Survey
Acceptance Criteria	The majority of survey responses from firms which voluntarily provided records affirm that providing such records facilitated the inspection process.	
Summary of Results	The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. A total of 42 inspections were conducted during the Study. Subsequent to the conclusion of the inspection, the most responsible person at each of the 42 inspected firms who was directly involved in the inspection was mailed an OMB approved Customer Satisfaction Survey. They were invited to voluntarily provide their views on the QSIT by completing and returning the survey form. The survey form contained the multi-part question: "Did your company receive advance notification of the inspection? Yes [ ] No [ ] If yes, were copies of records voluntarily provided to the investigator by your firm prior to the initiation of the inspection? Yes [ ] No [ ] If yes, which records were voluntarily provided? Did providing such records facilitate the inspection process? Yes [ ] No [ ] Please explain. ___" A total of 19 (45%) industry responses were received. A tabulation of individual responses is attached. It was determined that 18 (95%) of the 19 responding firms received advance notification c the inspection. Records were voluntarily provided by 16 (89%) of those 18 firms. A total of 15 (94%) of those 16 firms stated that providing such records facilitated the inspection process. *(1 (6%) response was No. The firm explained, "Believe auditor did nc have time to review prior to inspection."*	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments		
Activity Champion(s)	Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332)	

Item # G1B (Activity 3)

QUALITY SYSTEM INSPECTION TECHNIQUE (QSIT) CUSTOMER SATISFACTION SURVEY question:

Part 1 Did your company receive advance notification of the inspection? Yes [ ] No [ ]
Part 2 If yes, were copies of records voluntarily provided to the investigator by your firm prior to the initiation of the inspection? Yes [ ] No [ ]
Part 3 If yes, which records were voluntarily provided?
Part 4 Did providing such records facilitate the inspection process? Yes [ ] No [ ]
Part 5 Please explain.

TABULATION of RESPONSES

PART 1			PART 2		PART 3	PART 4		PART 5
Form	Y	N	Y	N	Records Provided	Y	N	Comments
1	X		X		Quality Policy Manual, Quality System Procedures	X		It allowed the inspector the chance to become familiar with our entire Quality System.
2	X		X		Quality Manual	X		
3	X		X		Quality Plan, Quality Manual, MGMT Review Procedure, Internal Audit Procedure, Design Control Proc.	X		Investigator had questions already formulated upon arrival.
4		X						
5	X		X		Quality Manual, Organizational Chart, Quality System SOPs	X		The auditor was ready to start upon arrival to our facility.
6	X		**		QA manual and Management Review Procedure	X		I think it helped the investigator prepare questions.
7	X		X		Policy & Procedures Manuals	X		Placed both the inspector and the firm on the same plane and allowed specific, focused questions.
8	X		X		* Quality Manual	X		The inspector reviewed the manual before the inspection so she could ask and probe the pertinent questions.
9	X		X		Quality Business Manual		X	Believe auditor did not have time to review prior to the inspection.
10	X			X				We offered to provide documents, but the investigator declined.
11	X		X		Top level systems documents: Quality Policy, Prod. Dev. Specs., Org. Charts, etc.	X		By reviewing these doc. Prior to inspection, the inspector already had the framework to design specific areas to audit. He could target specific areas where further clarification or doc. was needed.
12	X		X		All Procedure Manuals	X		The auditor knew areas he wanted to focus on prior to his arrival.
13	X			X				
14	X		X		SOP's for Quality Accountabilities, Quality Review, Audits, Calibration, Preventive Maintenance, and Validation	X		He arrived with basic understanding of * operations.
15	X		X		Quality Manual	X		Inspector had already reviewed and saw some concerns.
16	X		X		Quality Manual/Level I	X		Providing records prior to his arrival allowed

PART 1			PART 2		PART 3	PART 4		PART 5
Form	Y	N	Y	N	Records Provided	Y	N	Comments
					Policies			the investigator an insight to our quality systems.
17	X		X		Quality Manual	X		The inspector began the audit with a good "Macro" view of our Quality System.
18	X		X		Quality System Procedures Manual	X		The inspector was familiar with our Quality System when she arrived, so it was easier to explain how the overall system is structured.
19	X		X		Quality System Manual, and all procedures for Design Control	X		Sending the Quality System Manual and the Design Control procedures seemed to facilitate the inspection in that there was no Quality System Manual review on-site. I assume this was reviewed prior to inspection. The inspector seemed knowledgeable about Design Control System when the system was reviewed.

*The name of the firm was deleted to maintain confidentiality of the response.
** A specific Yes/No answer was not provided on the form. However, the response to Part 3 identified records that had been provided. Therefore, for this survey Form a "Yes" response to Part 2 will be included in the total.

TOTALS

Did your company receive advance notification of the inspection?
Yes 18 No 1

→ If yes, were copies of records voluntarily provided to the investigator by your firm prior to the initiation of the inspection?
Yes 16 No 2

→ Did providing such records facilitate the inspection process?
Yes 15 No 1

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
G1B (Activity4)	Decrease total time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	Responses by investigators to a question on an Evaluation Form.
Scope and nature of the process to be followed.[2]	During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections. Investigators will provide input into evaluating the QSIT b completing an Evaluation Form for each QSIT inspection conducted during the Study. The effect of the use of QSIT in increasing inspectional efficiency and thus decreasing inspectional time will be determined by the following Evaluation Form question: "Did use of the QSIT result in a more efficient inspection? Yes __ No __ Comments _____ ..." Responses will be tabulated and analyzed. Overall responsibility for this activity: G. Layloff (HFR-SW450) and T. Wells (HFZ-332)	
Acceptance criteria (if known)	The majority of responses affirm that the use of QSIT resulted in a more efficient inspection.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**		This activity provides a direct measurement on whethe use of the QSIT approach resulted in a more efficient inspection. A more efficient inspection correlates with decrease in inspectional time.
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.		This pre-deployment activity allows investigators (internal stakeholders) to provide input into the assessment of this goal.

Rev.12/18/98

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
G1B	Decrease total time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
4	Test	Responses by investigators to a question on an Evaluation Form
Acceptance Criteria	The majority of responses affirm that the use of QSIT resulted in a more efficient inspection.	
Summary of Results	The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. The investigators provided input into evaluating the QSIT by completing an Evaluation Form for QSIT inspections conducted during the Study. The investigator's input into the assessment of this goal was obtained through responses to the Evaluation Form question: "Did use of the QSIT result in a more efficient inspection? Yes __ No __ Comments___..." A total of 42 QSIT inspections were conducted during the Study. An Evaluation Form was submitted for each inspection. A tabulation of individual responses is attached. Responses to the question were as follows: Yes 34 (81%) No 2 (5%) Other 6 (14%) *(2 responses were – both Yes and No, 1 response was - Not sure, and 3 responses did not provide a specific yes or no answer.)*	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments		
Activity Champion(s)	Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332)	

Item # G1B (Activity 4)

INVESTIGATOR QSIT EVALUATION FORM question:

Did use of the QSIT result in a more efficient inspection? Yes __ NO __ Comments ____

TABULATION of RESPONSES

Inspection Code	Yes	No	Other	Comment	*
1A1			None	More efficient in that QSIT calls out exactly what to look at.	B
1A2	X			More efficient in these 4 areas.	B
1A3	X				B
1A4	X				B
1B1	X			I did concentrate on specific areas.	B
1B2	X			I was able to go directly to the prescribed information and not search for areas I might want to cover.	B
1B3	X			I efficiently covered the areas prescribed.	A
1C1	X			I was able to finish the inspection in a more timely fashion.	A
1C2	X				A
1C3	X			Yes, I took less time conducting this inspection using the QSIT method of inspection. It would have taken me longer to complete this inspection, if I had used the traditional method of inspection.	A
1C4	X			I spent less time conducting this inspection, than I would have spent conducting an inspection under the traditional method of inspection. If the objective was to spend less time vs. conducting a thorough inspection, then it worked.	A
1D1			None	I think the time was well spent and I don't believe I left any product problems behind. However, I believe there are additional cGMP/QSR problems that I didn't identify, which when taken in their totality could have resulted in an OAI classification. Because of that, I made a concerted effort to explain the importance of adequate internal quality audits and top management's involvement/commitment in identifying and correcting other deficiencies.	C
1D2	X				C
1D3	X				C
1D4	X				C
2A1		X		It is difficult to see the difference in this inspection. Firm did not have many of the required procedures.	A
2B1		X		I sometimes had to re-review material (procedures, complex scenarios) on issues that cut across subsystems. Lost some opportunities to apply linked and dual system review techniques that presented themselves.	C
2B2			Yes and No	In part as it established a focus, but the sequence of subsystem review was awkward and forced some re-reviews.	C
2B3			Yes and No	It does define a focus, but the sequence of review does not always fit the natural flow. Would be more efficient if allowed to follow the natural course of emerging conditions.	C
2C1	X			Not so much during the first inspection, but I suspect each inspection will become more efficient as I get more familiar with the format.	C

Inspection Code	Yes	No	Other	Comment	*
2C2	X				C
2C3	X			Helps to focus.	C
2C4	X				C
2D1	X			Mainly because QSIT simply requires a less detailed inspection. I like not having to do a Design Control report.	B
2D2	X			In terms of time - yes. In terms of consumer protection, I'm not sure about that.	B
2D3	X			More efficient – as defined by what? If just time – yes. If consumer protection – maybe not.	B
2D4	X			Quicker, but less comprehensive.	B
3A1	X				C
3A2	X				C
3A3	X				C
3A4	X			Even with the firm located approximately 2 ½ hours (one way) from the district office, I was still able to make significant observations in 3/4 focused areas. Includes an incomplete recall of two lots of orthopedic screws (misbranded) now being addressed by the firm. There still may be other problems at the firm in areas I did not cover.	C
3B1			None	Number of processes covered – 6… As mentioned above, this PMA EI covered various procedures and validations. During a non-PMA EI, not as many procedures and/or validations may be covered. Also, this was the first EI utilizing the system which could not be used to its full capabilities. The use of the floe charts did enable a functional reference system.	C
3B2	X			It is under Design Control that I have not been fully able to evaluate with the 2 EIs done so far as neither firm have utilized the full design control procedures. Specifically, under #2, paragraph 3 it states, "Review the firm's design control procedures and verify that they address the specific requirements of the regulation." All of 820.30 is to be covered for the review of the firm's DC SOP. Would it be better to use a modified DCR to utilize a checklist type review, or modify this QSIT section more?	C
3B3	X				C
3B4	X			By the end of the inspection, it was felt the firm was fully covered under the QS/GMPs utilizing the QSIT approach.	C
3C1	X				B
3C2	X				B
3C3	X				B
3C4	X				B
3D1			Not sure		A
3D2	X				A
3D3	X				A
Total	34	2	6		

* Time in position as investigator, where A = 1-5 years, B = 6-10 years, and C >10 years

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
G1B (Activity 5)	Decrease total time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	Responses by investigators to a multi-part question on an Evaluation Form
Scope and nature of the process to be followed.[2]	In order to facilitate the inspection, the QSIT directs the investigator, during the pre-announcement of the inspection, to request copies of the firm's Quality Policy and high level Quality System Procedures (including management Review Procedures), Quality manual, Quality Plan or equivalent documents to preview prior to the inspection. Such facilitation will result in increased efficiency of the inspection and lead towards a decrease in the total time for conducting inspections. During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections. Investigators will provide input into evaluating the QSIT b completing an Evaluation Form for each QSIT inspection conducted during the Study. The Form will contain the multi-part question, "Was the inspection pre-announced? Yes ___ No ___ If yes, were records voluntarily provided by the firm prior to the initiation of the inspection? Yes ___ No ___ If yes were the records reviewed? Yes ___ No ___ If yes, how much time was expended to review those records? ___ Did this review increase the efficiency of the inspection? Yes ___ No ___ Comments ___ ..." Responses will be tabulated and analyzed. Overall responsibility for this activity: G. Layloff (HFR-SW450) and T. Wells (HFZ-332)	
Acceptance criteria (if known)	The majority of responses affirm that the review increased the efficiency of the inspection.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**	This activity provides a direct measurement on wheth reviewing records prior to the initiation of the inspection resulted in a more efficient inspection. A more efficient inspection correlates with a decrease in inspectional time.	
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.	This pre-deployment activity allows investigators (internal stakeholders) to provide input into the assessment of this goal.	

Rev.12/18/98

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
G1B	Decrease total time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
5	Test	Responses by investigators to a multi-part question on an Evaluation Form
Acceptance Criteria	The majority of responses affirm that the QSIT tools were useful.	
Summary of Results	The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. The investigators provided input into evaluating the QSIT by completing an Evaluation Form for QSIT inspections conducted during the Study. The investigator's input into the assessment of this goal was obtained through responses to the multi-part question, "Was the inspection pre-announced? Yes ___ No ___ If yes, were records voluntarily provided by the firm prior to the initiation of the inspection? Yes ___ No ___ If yes, were the records reviewed? Yes ___ No ___ If yes, how much time was expended to review those records? ___ Did this review increase the efficiency of the inspection? Yes ___ No ___ Comments ___..." A total of 42 QSIT inspections were conducted during the Study. An Evaluation Form was submitted for each inspection. A tabulation of individual responses is attached. It was determined that 38 (90%) of the 42 inspections were pre-announced. Records were provided voluntarily for review by 30 (79%) of those 38 firms. Records from at least 20 (67%) of those 30 firms were reviewed. At best, records from 28 (93%) of those 30 firms or 28 (66.7%) of the 42 total firms were reviewed. When reviews were conducted, the average time expended to review records was 4 hours. Since record review only took place, at best, only 66.7% of the time, the overall average time expended to review records was 2.7 hours. A total of 23 (96%) out of 24 responses stated the review increased the efficiency of the inspection. *(1 (4%) response was No.)*	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments		
Activity Champion(s)	Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332)	

Item # G1B (Activity 5)

INVESTIGATOR QSIT EVALUATION FORM multi-part question:

Part 1 Was the inspection pre-announced? Yes ___ No ___
Part 2 If yes, were records voluntarily provided by the firm prior to the initiation of the inspection? Yes ___ No ___
Part 3 If yes, were the records reviewed? Yes ___ No ___
Part 4 If yes, how much time was expended to review those records?
Part 5 Did this review increase the efficiency of the inspection? Yes ___ No___
Part 6 Comments _____

TABULATION of RESPONSES

PART	1		2		3		4	5		6
Inspection Code	Y	N	Y	N	Y	N	Hrs.	Y	N	Comments
1A1	X		X							Slightly
1A2	X		X					X		
1A3	X		X					X		
1A4	X		X					X		
1B1	X		X		X		3	X		Somewhat, however they were not actually following these procedures so I had to spend extra time evaluating their controls.
1B2	X			X						There was not enough time to receive the records prior to the inspection.
1B3	X			X						When this inspection was pre-announced there was not enough time to receive the document by mail before starting the inspection.
1C1	X		X		X		8		X	I think the review could have been performed in the firm without any additional time spent in the inspection. I am able to concentrate better in the firm while reviewing records. I get a lot of interruptions while I am in the office.
1C2	X		X			X				I did not have time to review the records due to the scheduling problems. As it turned out, this inspection only took 2 days to complete.
1C3	X		X		X		4	X		
1C4	X		X		X		6	X		I found that covering the design control subsystem was easier, having read the SOPs prior to starting the inspection.
1D1	X		X		X		4	X		The pre-inspectional review increased the efficiency of the inspection because I did not have to devote in the plant time to review them.
1D2	X		X		X		3	X		
1D3	X		X		X		2	X		The pre-inspectional review had a minimal impact on the efficiency of the inspection because the firm is very small and did not need extensive procedures.
1D4	X		X		X		3	X		
2A1	X			X						Firm did not have documents available. Discussed with owner and decided to cover during inspection.

PART	1		2		3		4	5		6
Inspection Code	Y	N	Y	N	Y	N	Hrs.	Y	N	Comments
2B1	X			X						Records (ISO Quality manual) was obtained 1st day of the inspection and reviewed back at the office prior to continuing the inspection. (Review 6 hours) These records are high level and tend to be generic – like particularly outside the context of the firm after unique implementation. I prefer to review them in concert with review of subsystem(s).
2B2		X								
2B3	X			X						Copies of the quality manual were included with the PMA sup. Subject of this inspection and were reviewed along with PMA review prior to the inspection. Sections of the quality procedures need to be requirements during and throughout the inspection to be efficient.
2C1	X		X			X				Due to the holiday and no mail delivery on 10/13, firm couldn't get the records to me in time.
2C2	X		X		X		2	X		This definitely helped speed up the inspection.
2C3	X		X		X		4	X		But I still had questions and needed further clarifications
2C4	X		X		X		3	X		
2D1		X								This was a regulatory follow-up inspection. (W/L)
2D2	X		X		X		2	X		Quality manual. Pre-inspection review was helpful, but not a replacement for covering the procedures during the inspection.
2D3	X		X		X		2	X		Still needed to review them at the firm in light of the inspection findings.
2D4		X								Regulatory follow-up
3A1	X		X		X					Somewhat
3A2	X		X		X		5	X		Extremely
3A3	X		X							
3A4	X		X							Review of procedures, along with the factory jacket, enabled me to formulate questions/concerns of the firm's established procedures in the district office instead of expending time at the firm.
3B1	X			X						Only the manufacturing sections of the PMA were obtained from CDRH.
3B2	X			X						EI made pursuant to obtain initial recall information and per the district's 25 month list. Firm had notified --- of their recall. First 2 days of EI was spent obtaining the recall information. Personal injury delayed the continuation of the EI for two weeks.
3B3	X			X						
3B4		X								
3C1	X		X		X		8	X		
3C2	X		X		X		5	X		I felt this expedited the process & allowed me the basic understanding prior to walking into the firm.
3C3	X		X		X		4	X		
3C4	X		X		X		4	X		
3D1	X		X		X		4-6	X		Not all of the applicable records were sent upon first request.
3D2	X		X					X		

PART I	1		2		3		4	5		6	
Inspection Code	Y	N	Y	N	Y	N	Hrs	Y	N	Comments	
3D3	X		X					X			A

- Time in position as investigator, where A = 1-5 years, B = 6-10 years, and C >10 years

TOTALS

Was the inspeetion pre-announced?
Yes 38 No 4

→ If yes, were records voluntarily provided by the firm prior to the initiation of the inspection?
Yes 30 No 8

→ If yes, were the records reviewed?
Yes 20 No 2 (No response - 8)

→ If yes, how much time was expended to review those records?
4 Hours (Avg. Time reported per 19 responses)

Did this review increase the efficiency of the inspection?
Yes 23 No 1 (No response – 6)

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
G1B (Activity 6)	Decrease total time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	Responses by investigators to a multi-part question on an Evaluation Form
Scope and nature of the process to be followed.[2]	The QSIT Handbook was designed to provide investigators with information on what needs to be accomplished during a comprehensive medical device inspection, how it is to be accomplished and why it needs to be accomplished. The Handbook was developed to be a useful tool for investigators that would facilitate the inspection process and thus decrease inspectional time. During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections. Investigators will provide input into evaluating the QSIT b completing an Evaluation Form for each QSIT inspection conducted during the Study. The Form will contain the multi-part question, "Were the QSIT tools (Handbook – Objectives, purpose/importance statements, narratives, flowcharts, sampling plans) useful during the inspection? Yes ___ No ___ If yes, which tools were most useful and how were they helpful?" Responses will be tabulated and analyzed. Overall responsibility for this activity: G. Layloff (HFR-SW450) and T. Wells (HFZ-332)	
Acceptance criteria (if known)	The majority of responses affirm that the QSIT tools were useful.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**	This activity provides a direct measurement on wheth the QSIT tools were useful. Such usefulness indirectly correlates with a decrease in inspectional time.	
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.	This pre-deployment activity allows investigators (internal stakeholders) to provide input into the assessment of this goal.	

Rev.12/18/98

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
G1B	Decrease total time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
6	Test	Responses by investigators to a multi-part question on an Evaluation Form
Acceptance Criteria	The majority of responses affirm that the QSIT tools were useful.	
Summary of Results	The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. The investigators provided input into evaluating the QSIT by completing an Evaluation Form for QSIT inspections conducted during the Study. The investigator's input into the assessment of this goal was obtained through responses to the multi-part question: "Were the QSIT tools (Handbook – Objectives, purpose/importance statements, narratives, flowcharts, sampling plans) useful during the inspection? Yes ___ No ___ If yes, which tools were most useful and how were they helpful?" A total of 42 QSIT inspections were conducted during the Study. An Evaluation Form was submitted for each inspection. A tabulation of individual responses is attached. Responses to the question were as follows: Yes 42 (100%) No 0 (0%)	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments		
Activity Champion(s)	Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332)	

Rev. 2/12/99

Item # G1B (Activity 6)

INVESTIGATOR QSIT EVALUATION FORM question:

Were the QSIT tools (Handbook – Objectives, purpose/importance statements, narratives, flowcharts, sampling plans) useful during this inspection? Yes __ NO __
If yes, which tools were most useful and how were they helpful?

TABULATION of RESPONSES

Inspection Code	Yes	No	Other	Tools Most Useful and How They Were Helpful	*
1A1	X			Good amount of detail in the handbook.	B
1A2	X				B
1A3	X				B
1A4	X				B
1B1	X			QSIT Handbook, and the Turbo 483 items.	B
1B2	X			The QSIT Handbook is the most helpful.	B
1B3	X			QSIT Handbook	B
1C1	X			The handbook was very useful and very easy to use.	A
1C2	X			The inspection handbook was very easy to read and easy to follow.	A
1C3	X			I call the QSIT Handbook my bible. It is very easy to use and very helpful.	A
1C4	X			I found that the QSIT Handbook was very useful. It was very easy to read and it kept me focused.	A
1D1	X			I found myself relying on the flowcharts because they are concise and compact enough for ready reference. Then, I would go to the narrative section if I needed more detailed information	C
1D2	X			The flowcharts and sampling plans were the most useful. The sampling plans helped limit the number of records I needed to review. The simplistic format of the flowchart made it easy to reference specific areas as needed and then served as a gateway to the narrative sections if I needed additional explanations.	C
1D3	X			The flowchart was the most useful tool. Very limited use was made of the sampling plans because the firm did not have very many records for review.	C
1D4	X			The flowchart and sampling tables were most useful because they helped narrow the focus of the inspection.	C
2A1	X			I did not follow objectives in exact order, but covered all objectives – learning curve.	A
2B1	X			Helped to focus on and complete all aspects of the QSIT requirements.	C
2B2	X			I used the sampling table. It helped maintain focus. The CAPA section was useful but problematic. Helped to define the scope of my review, but the narrative suggests a wider review with more sampling then is on the Decision flow chart.	C
2B3	X			The various subsystem questions and narrative were helpful for keeping the inspection on course with QSIT requirements.	C
2C1	X			The handbook was the most useful, especially with this being my first QSIT inspection. I followed it pretty closely during the inspection.	C
2C2	X			QSIT handbook – I followed it faithfully	C

Inspection Code	Yes	No	Other	Tools Most Useful and How They Were Helpful	*
2C3	X			QSIT handbook was the most useful – it helps structure the course of the inspection.	C
2C4	X			Most useful – QSIT Handbook – specifically the narratives	C
2D1	X			I relied mainly on the objectives, then referred to the narrative as needed.	B
2D2	X			Guided the order of inspection coverage. Served as reminder of areas to cover.	B
2D3	X			List of Objectives was most helpful	B
2D4	X			Objectives list	B
3A1	X			Narrative and flowchart were most helpful – kept EI focused	C
3A2	X			Always the narrative/flowchart	C
3A3	X				C
3A4	X			The narrative and the sampling plan kept the inspection focused and timely. The sampling plan reduced the quantity of records I would have reviewed during a routine inspection. Even though the number of records were reduced, I was still able to make significant observations in the focused areas (e.g. management control, production and process controls).	C
3B1	X			The flow charts were utilized primarily after a copy of them were modified to include keywords for reference of the narrative sections for further follow up and/or clarification.	C
3B2	X			The flowchart again was found the most convenient tool for staying on track but the handbook had to be utilized more during the CAPA section to keep from deviating. The sampling plan Table 1, Confidence Level A for a 11 record sampling size was utilized on the in-process tip component record, complaint, non-compliance, in-compliance, trending, corrective action, and training record reviews. However, during P&PC, while reviewing the heat sealer validations and maintenance, I had to return to the tip component records that had already been reviewed and view several additional tip component history records to determine the extent of the deviation (FD483 #1) for all size tips as only the size 50 & 56 French were originally covered. In essence, even though the minimum no. of records were reviewed and no deviations were found for the areas originally being reviewed, you may have to return to those records under P&PC and expand on them. This should be noted under P&PC for clarification purposes. (I hope this is clear. If not give me a call.) For firms that manufacture complex devices or utilize very technical and complex manufacturing processes. I would have trouble in the P&PC Section to select only one process. As mentioned in today's telecon, the CSO should have the option of doing at least two processes if needed to verify the firm is in compliance with QS/GMPs.	C
3B3	X			Again the flowcharts were mostly used with both the flowchart and the booklet being used under CAPA	C
3B4	X			All aspects of the handbook were utilized with the flowchart being used as the main potion of the handbook with the narrative portion being used for clarification. The sampling tables were used extensively.	C
3C1	X			Narratives & flowcharts	B
3C2	X				B
3C3	X			Narratives	B
3C4	X				B

Inspection Code	Yes	No	Other	Tools Most Useful and How They Were Helpful	*
3D1	X			Flowchart is very helpful	A
3D2	X				A
3D3	X				A
Total	42	0	0		

* Time in position as investigator, where A = 1-5 years, B = 6-10 years, and C >10 years

G2A

Increase Focus

FDA 483

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
G2A (Activity 1)	Increase the focus of FDA 483 listed Quality System deficiencies on key elements of the major subsystems of the Quality System with linkages to the remaining subsystems.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	1. Comparison of FDA 483 items to the steps in the QSIT Handbook flowcharts. 2. Subsystems associated with QSIT FDA 483 items vs non-QSIT FDA 483 items. 3. QSIT OAI rate vs non-QSIT OAI rate.
Scope and nature of the process to be followed.[2]	During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections. Beginning the week of 1/11/99, the FDA 483s for the QSIT Study inspections will be reviewed by C. Tylka, HFZ-320. The QS regulation FDA 483 items will be compared to the steps of the flowcharts in the QSIT Handbook. The flowchart steps correspond to the key elements of the firm's Quality System that are to be evaluated when performing a QSIT inspection. The results of the reviews will be tabulated and assessed. The match of the FDA 483 items to the flowchart steps will indicate that the QSIT FDA 483 items focused on the key elements of the major subsystems. The subsystems associated with the 10 most prevalent QSIT FDA 483 items will also be compared to the subsystems associated with the 10 most prevalent QS regulation FDA 483 items from non-QSIT inspections conducted during the period 6/97-6/98. Design Control deficiencies during this period were listed as Areas of Needed Improvement. However, they were tracked in the CDRH database and will be included in this evaluation. The FDA 483 items from non-QSIT inspections will be identified from the FDA483 database maintained by HFZ-305. The results will be tabulated and assessed. The correspondence of FDA 483 items to the 4 major subsystems (Management, Design, CAPA and PAPC) will indicate that the FDA 483 focused on the major subsystems of the regulation. An increase in the correspondence of QSIT FDA 483 items vs non-QSIT FDA 483 items will indicate an increase in focus on the major subsystems. The OAI rate associated with QSIT inspections, based on classifications by QSIT trained Compliance Officers using the QSIT Draft Part V of the Compliance Program 7382.830, will be compared to non-QSIT inspections performed during FY 98. The OAI rate for FY 98 will be obtained from HFZ-305. QSIT was designed to focu the inspection on the assessment of the key elements of the Quality System. FDA 483s resulting from the inspections should also contain items which focus on those key elements. Inspections conducted using QSIT, an approach which focuses on key elements, should yield at least the same or greater violation (OAI) rate as inspections conducted using the non-QSIT approach. Overall responsibility for this activity: G. Layloff (HFR-SW450) and T. Wells (HFZ-332)	
Acceptance criteria (if known)	1. The majority of the FDA 483 items correspond to the steps of the QSIT flowchart. 2. There is more of a correspondence of the QSIT FDA 483 items with the major subsystems of the QS regulation then non-QSIT FDA 483 items. 3. The OAI rate for QSIT inspections is at least equal to or greater then that of non-QSIT inspections.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**		This activity provides a direct and objective measurement on whether QSIT FDA 483s focus on the key Quality System elements. It indirectly compares the focus of QSIT FDA 483s to non-QSIT FDA 483s.
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.		This pre-deployment activity will demonstrate if the QSIT FDA 483s were focused. It will indirectly measure whether or not the FDA 483 focus has increased.

Rev.12/18/98

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
G2A	Increase the focus of FDA 483 listed Quality System deficiencies on key elements of the major subsystems of the Quality System with linkages to the remaining subsystems.	
Activity #	**Type of activity** (test or analysis)	**Parameter(s)** to be measured
1	Test	1. Comparison of FDA 483 items to the steps in the QSIT Handbook flowcharts. 2, Subsystems associated with QSIT FDA 483 items vs non-QSIT FDA 483 items. 3. QSIT OAI rate vs non-QSIT QAI rate.
Acceptance Criteria	1. The majority of the FDA-483 items correspond to the steps of the QSIT flowchart. 2. There is more of a correspondence of the QSIT FDA 483 items with the major subsystems of the QS regulation then non-QSIT FDA 483 items. 3. The OAI rate for QSIT inspections is at least equal to or greater then that of non-QSIT inspections.	
Summary of Results	The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. A total of 42 QSIT inspections were conducted during the Study. A total of 28 FDA 483s containing a total of 200 items were issued during those inspections. The FDA 483s were reviewed by HFZ-320 and the individual FDA 483 items were compared to the steps of the flowcharts in the QSIT Handbook. The flowchart steps correspond to the key elements of the major subsystems of the Quality System A tabulation of the results is attached. Part 1 A total of 178 of the 200 FDA 483 items were found to match the QSIT Handbook flowchart steps. Of the remaining 22 items, 10 were directly linked to CAPA and PAPC flowchart steps. The remaining 12 items appear to be linked to PAPC flowchart steps. This activity has demonstrated that the QSIT FDA 483 items focused on the key elements of the major subsystems of the Quality System. Part 2 A comparison of the 10 most prevalent FDA 483 items from QSIT and non-QSIT inspections found the QSIT items to correspond more with the major subsystems as follows: QSIT Inspections: Management 40%, CAPA 30%, PAPC 20%, and D&R 10% Non-QSIT Inspections: CAPA 50%, PAPC 30%, and D&R 20% This increase in the correspondence indicates an increase in focus on the major subsystems. Part 3 A total of 9 QSIT inspections were classified OAI, using the QSIT Draft Part V of the Compliance Program 7382.830, by QSIT trained Compliance Officers. The OAI rate for QSIT inspections classified in this manner was 21%. The OAI rate for FY 98 was 16%. This equates to an increase in the OAI rate of 31%.	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments		
Activity Champion(s)	Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332)	

Attachment 1 - Item # G2A (Activity 1)

Part 1

FDA483 Review Results
(QS Regulation Deficiencies)

	CODE	1 A 1	1 A 2	1 A 3	1 A 4	1 B 1	1 C 1	1 C 3	1 C 4	1 D 1	1 D 2	1 D 3	1 D 4	2 A 1	2 B 1	2 B 2	2 C 4	2 D 2	2 D 3	2 D 4	3 A 1	3 A 4	3 B 1	3 B 2	3 B 3	3 B 4	3 C 2	3 C 3	3 D 3	TOTAL
MGMT	1				3		1			1				1								1	3		1		1			12
	2										2	1																	1	4
	3a																													0
	3b					1		1			2											1	2			1				8
	4a	1			1																		1				1	1		5
	4b																													0
	5	2				1		2		1	1	2		1													1	1		12
	6	2	1		1	1		2		2	2	1					1						1	1		1				16
DESIGN	1							1																						1
	2				1					1	1																			3
	3																													0
	4																													0
	5			1																										1
	6						1																		1					2
	7			1					1																					2
	8										2																			2
	9						1																							1
	10																													0
	11								1		1																			2
	12																				1									1
	13	1		1			2														2							1		7
	14		1												1									1	1					4
	15																													0

57

	CODE	1 A 1	1 A 2	1 A 3	1 A 4	1 B 1	1 C 1	1 C 3	1 C 4	1 D 1	1 D 2	1 D 3	1 D 4	2 A 1	2 B 1	2 B 2	2 C 4	2 D 2	2 D 3	2 D 4	3 A 1	3 A 4	3 B 1	3 B 2	3 B 3	3 B 4	3 C 2	3 C 3	3 D 3	TOTAL
CAPA	1	1			3		1			1				1		1									1		1	2	12
	2			2			1	2			1					2			1		1		1							11
	3																													0
	4																							1						1
	5						1																		1					2
	6							3			1					2			2		1									9
	7			1					1								1					1			3					7
	8		2					1																						3
	9	1						1							2															4
	10																				1									1
PAPC	1a																													0
	1b																													0
	2				1	2	1	1	4	1	1		2	1				1	2		3	1	1	3	1	1		1	1	29
	3a					1																								1
	3b	1						1		1											3		1	1						8
	4								1												1	1								3
	5																		1			1								2
	6																			1						1				2
Other			1[1]				4[1]			1[1]	1	5		1							2[1]	3			2[2]	1				22
Total[2]		9	5	6	10	6	13	15	8	9	15	9	2	5	3	5	2	1	6	2	15	9	10	6	6	11	3	5	4	200

[1] Linkage between PAPC and D&R

[2] Linkage between CAPA and D&R

Attachment 1 Item # G2A (Activity 1)

Part 2

Review of the QS Regulation FDA 483 items from QSIT and non-QSIT inspections found the 10 most prevalent items to be associated with the following subsystems:

QSIT Inspections
Management (40%)
CAPA (30%)
PAPC (20%)
Documents & Records (10%)

Non-QSIT inspections
CAPA (50%)
PAPC (30%)
Documents & Records (20%)

Part 3

The following QSIT inspections were classified OAI, using the QSIT Draft Part V of the Compliance Program, by the QSIT trained Compliance Officers who participated in the Study:

1. 1A1	4. 1C4	7. 1D3
2. 1A4	5. 1D1	8. 2D3
3. 1C3	6. 1D2	9. 3B4

There were 42 inspections conducted during the Study. The QAI rate for QSIT inspections using the QSIT Draft Part V was 21%.

The OAI rate for FY 98 was 16%.

G2B

Increase Focus

Inspection Approach

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
G2B (Activity 1)	Increase the focus of the approach to conducting Quality System inspections on the key elements of the major subsystems of the Quality System with linkages to the remaining subsystems.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	Industry responses to a multi-part question on a Customer Satisfaction Survey
Scope and nature of the process to be followed.[2]	During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections. The most responsible person at each of the inspected firms who was directly involved in the inspection will b mailed an OMB approved Customer Satisfaction Survey. They will be invited to voluntarily provide their views on the QSIT by completing and returning the survey form. The survey form will contain the multi-part question, "Did the QSIT focus on the key elements of your quali system? Yes [ ] No [ ] If Yes, how did this focus prove beneficial to your firm? Please give examples." Responses will be tabulated and analyzed. Overall responsibility for this activity: G. Layloff (HFR-SW450) and T. Wells (HFZ-332)	
Acceptance criteria (if known)	The majority of survey responses affirm that the QSIT focused on the key Quality System elements.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**	This activity provides a direct and objective measurement on whether the QSIT approach focused the key Quality System elements. It does not directly compare QSIT to the current FDA auditing technique	
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.	This pre-deployment activity allows firms (stakeholders) to provide input into the assessment of this goal.	

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
G2B	Increase the focus of the approach to conducting Quality System inspections on the key elements of the major subsystems of the Quality System with linkages to the remaining subsystems.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
1	Test	Industry responses to a multi-part question on a Customer Satisfaction Survey
Acceptance Criteria	The majority of survey responses affirm that the QSIT focused on the key Quality System elements.	
Summary of Results	The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. A total of 42 inspections were conducted during the Study. Subsequent to the conclusion of the inspection, the most responsible person at each of the 42 inspected firms who was directly involved in the inspection was mailed an OMB approved Customer Satisfaction Survey. They were invited to voluntarily provide their views on the QSIT by completing and returning the survey form. The survey form contained the multi-part question: "Did the QSIT focus on the key elements of your quality system? Yes [ ] No [ ] If yes, how did this focus prove beneficial to your firm? Please give examples." A total of 19 (45%) industry responses were received. A tabulation of individual responses is attached. Responses to the question were as follows: Yes 19 (100%)	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments		
Activity Champion(s)	Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332)	

Item # G2B (Activity 1)

QUALITY SYSTEM INSPECTION TECHNIQUE (QSIT) CUSTOMER SATISFACTION SURVEY question:

Did the QSIT focus on the key elements of your quality system? Yes [ ] No [ ]
If yes, how did this focus prove beneficial to your firm? Please give examples.

TABULATION of RESPONSES

Form	Yes	No	Other	Comment
1	X			We focused on the CAPA section that demonstrated that we actively corrected problems.
2	X			It provided an independent audit to locate shortcomings.
3	X			Findings resulted in improved procedures and processes. Better understanding of Design Controls. Streamlined Management Controls process.
4	X			It focused on key elements (i.e., Management Controls, Design Controls, Corrective and preventive Actions, and Production and Process controls) and thus limited the length of the investigation based on those elements.
5	X			It allowed us to pull the appropriate documents quicker with less confusion on the direction the audit was moving.
6	X			QSIT seems more concerned with the processes resulting in a product rather than a hunt for paperwork errors.
7	X			Provided clear focus for the investigation and help provide insight in areas of improvement for the firm.
8	X			Design Control is the most beneficial to us.
9	X			
10	X			It provided a more meaningful audit of the system than the 'bottom up' approach, and covered more items in a shorter timeframe. We feel we had a thorough audit that covered all subsystems.
11	X			Reinforced the areas that quality system is based on – our doc. system is based around these areas – same areas as other reg. Bodies focus on as well as internal audits.
12	X			It immediately directed us to areas we need to improve. The auditor knew we were insufficient in our written Quality Policy Statement and designated responsible individual.
13	X			Concentration on 4 key quality systems – concentration on system integrity & information analysis – review of CPA database
14	X			It helped us prepare specific documentation. Inspection conducted without surprises. Enabled us to make available specific technical support.
15	X			The auditor told me exactly what points she was going to review – so I had them assembled.
16	X			The QSIT did focus on the key elements, however, it had neither a positive nor negative effect on the inspection.
17	X			The focus helped in scheduling personnel to be available, and in giving us a good review of our system procedures.
18	X			Our Quality System is structured as a complete system so the inspection focus was well matched with our implementation.
19	X			This approach challenged the main quality systems and how they work together.
TOTAL	19	0	0	

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
G2B (Activity 2)	Increase the focus of the approach to conducting Quality System inspections on the key elements of the major subsystems of the Quality System with linkages to the remaining subsystems.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Analysis	Inspectional Objectives described within the "QSIT Inspection Handbook"
Scope and nature of the process to be followed.[2]	Review and analysis of the process and qualifications of the individuals responsible for developing the QSIT objectives. Specifically, the process by which the QSIT was developed will be described in writing. The primary participants and contributors will be described and analyzed to ensure that their experiences, knowledge and skills demonstrate they are qualified to assess a quality system and determine key elements c major subsystems and their linkages. For FDA participant's this may be accomplished via a review of the individual's current C.V., resume, SF-171 or other documented evidence of their qualifications. For industr and consultants who have contributed, this analysis may be limited to a review of the individual's title and responsibilities including their representation to recognized trade or quality organizations. Overall responsibility for this activity: R. Ruff (HFR-CE350)	
Acceptance criteria (if known)	The process used to develop the QSIT provided for, considered, and implemented input from a diverse population of recognized and qualified quality professionals to ensure it focused on the key elements of a device manufacturer's quality system.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**		This activity will provide direct and objective evidenc that the inspectional focus of the QSIT is on the key elements of major quality system subsystems as determined by a diverse population of quality professionals.
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.		This pre-deployment activity will demonstrate that th inspectional focus of QSIT is on the key elements of major quality system subsystems through a direct review of objective evidence.

Rev.12/18/98

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome
G2B	Increase the focus of the approach to conducting Quality System inspections on the key elements of the major subsystems of the Quality System with linkages to the remaining subsystems.

Activity #	Type of activity (test or analysis)	Parameter(s) to be measured
2	Analysis	Inspectional Objectives described with the "QSIT Inspection Handbook"

Acceptance Criteria

The process used to develop the QSIT provided for, considered, and implemented input from a diverse population of recognized and qualified quality professionals to ensure it focused on the key elements of a device manufacturer's quality system.

Summary of Results

Attachment #'s 1A-1I are summaries of the qualifications of the FDA representatives to the QSIT development team. Provided below is a brief summary of several key considerations:

Name	Grade	Title	Duty Station	FDA Experience (yrs.)
Denise Dion	GS-13	Medical Device Expert	FDA/ORA/DEIO	14
Georgia Layloff	GS-13	Medical Device Specialist	FDA/ORA/STL	29
M. Chris Nelson	GS-13	Quality Systems Expert	FDA/CDRH/OC	9
Robert Ruff	GS-13	Medical Device Specialist	FDA/ORA/NWJ-DO	9
Kim Trautman	GS-15	GMP & Quality Systems Expert	FDA/CDRH/OC	8
Cory Tylka	GS-13	CSO (medical lasers)	FDA/CDRH/OC	19
Tim Wells	GS-14	Chief, Ob-Gyn, Reengr. Team Ldr.	FDA/CDRH/OC	23
Norm Wong	GS-14	Medical Device National Expert	FDA/ORA/DEIO	27
Allen Wynn	GS-13	CSO (Field Programs Branch)	FDA/CDRH/OC	22

Attachment 2 is a photocopy of a list of members and guests of FDLI's Ad Hoc Group for Quality System Inspections. This group represented a number of medical device manufacturers, trade organizations and consultants to the medical device industry and contributed on several occasions to the QSIT development project. Provided below is a summary of titles of members of the FDLI group:

V.P., Manager of Compliance
V.P., Global Quality Management
Principal (Consultant)
Executive Director (Consultant)
Director, Regulatory Compliance and Audit
Dir. of Continuous Improvement and Quality Systems
Dir. of Technology and Reg. Affairs (Trade Org.)
Ex. V.P. (Consultant)
V.P., Compliance & Quality Systems (Consultant)
Manager, Corporate Compliance
Quality Systems Champion
Dir. Research & Development
Special Counsel (Trade Org.)
Regulatory Affairs and Compliance Manager
Reg. Staff Manager, Med. Products Group

Attachment 3 is a summary of the QSIT development history. Attachment 3 documents that in addition to seeking input from the above referenced individual's, the QSIT development team sought input from the publi during an open public meeting and FDA medical device investigators representing a variety of experience levels.

Conclusion

The findings do [X] do not [ ] meet the acceptance criteria for this activity.

Additional Comments

Activity Champion(s) Robert G. Ruff, CSO (HFR-CE350)

Cc:
Bcc:
From: Denise Dion@DEIO@FDAORAHQ
Subject: BIO
Date: Tuesday, March 2, 1999 at 2:08:06 pm EST
Attach:
Certify: N

Education: Associate Degree - Emergency Medicine
Bachelor of Science: Biology (Co-ordinate major in Environmental Studies, Chemistry minor, Pre-Medical Curriculum)
Post-Graduate Masters Courses - Aquatic Ecology, Genetics, Microbiology

FDA History:

Investigator GS 7, 9, 11 - Detroit District 1985-1990
Investigator, GS-12 Biologics Specialist - Detroit District, 1990-1991
Investigator, GS-13 Regional Biologics Specialist - Dallas District, 1992-1994
Investigator, GS-13 Medical Device Expert - Division of Emergency and Investigational Operations, 1994-present

In current position, develops agency policy and procedures relative to the inspection and investigation of medical device establishments. Acts as expert resource for agency personnel relative to the inspection and investigation, etc. of medical device establishments. Performs high level inspection and investigations of medical device establishments.

Let me know how much more you really need.

Denise D. Dion
DEIO - Medical Device Group
) 827-5645

Georgia A. Layloff

FDA/St. Louis Branch Office
12 Sunnen Drive
Suite 122
St. Louis, MO 63143

Phone: 314-645-1167 x 121
email: glayloff@ora.fda.gov
Fax: 314-645-2969

EXPERIENCE

Investigator, St. Louis, MO — 1980 - Present

- Currently serves as a regional field expert in the area of medical devices. Expertise includes design control and premarket approval investigations, quality systems, and case development activities. Previously served as a medical device specialist (1993-1997) and also a journeyman investigator (1980-1993).
- Core member of the QSIT Team making significant contributions to all aspects of the project including development of the Handbook and CD computer based training. Subteam leader for the 6/98 Open Public Meeting. Co-subteam leader for the QSIT Study including training of field investigators and compliance officers participating in the Study. Co-subteam leader for the QSIT Validation project.
- Contributing member of the Design Control Inspectional Strategy Team which developed the strategies being utilized by FDA investigators in assessing compliance to design controls under the Quality System Regulation.
- Served as a member of the Audit Development CADRE that developed the specific criteria that is being used during the performance audits of FDA candidates for Level II medical device certification.
- Achieved Level II medical device certification and is also an active certification performance auditor.
- Consults and provides technical assistance to FDA management and staff including the Office of Criminal Investigations, and also industry representatives.
- Overall investigative activities have resulted in millions of dollars of voluntary industry corrections. Resulting legal actions have included prosecutions.
- Monitors and coordinates medical device program accomplishments and prepares workplans.
- Member of an FDA/industry team that designed the "Facilitating Effective Interaction" workshop and contributor to the resource guide for conducting such a workshop.
- Reviewed and evaluated domestic and foreign design control inspectional reports.
- Conducted undercover assignments.
- Organized and facilitated workshops and training sessions.
- Served as a subject matter expert to a Course Advisory Group for FDA's Basic Medical Device Course.
- Coordinated recall and emergency, registration and consumer complaint activities.

Investigator, Philadelphia, PA — 1977 - 1980

- Served as a journeyman investigator. Evaluated industry compliance while conducting complex medical device, including IVD, human and veterinary drug, and food inspections, investigations and sample collections. These included areas such as GMPs, sterility, bioresearch monitoring, fraud, pre and post award government purchase acceptances, product defect reports involving deaths and serious injuries and product recalls.
- Analyzed investigational results to determine assignment termination time and follow-up action.
- Voluntary industry corrections resulting from inspectional activities included the extension of a device recall to include over $1 million of product, and the initiation of a Class I device recall.
- Legal and administrative actions resulting from inspectional activities included product seizures and the issuance of Regulatory and Notice of Adverse Findings letters.
- Consulted and assisted compliance officers in case preparations.
- Issued and monitored inspectional assignments.
- Reorganized, updated and monitored registrations.

Chemist, Philadelphia, PA — 1970 - 1977

- Achieved the level of journeyman chemist.
- Conducted research in laboratory automation including system design and setup, and direct on-line interfacing, data acquisition and operation of multi-instrument/computer systems. Published findings and converted such systems to operational use.
- Served as analytical group leader.
- Served as Laboratory Management Systems Coordinator and Laboratory Computer System liaison within the district and with headquarters.
- Designed, developed and published analytical methods for autoanalyzers.

- Conducted method development, validation, and analyses of samples covering a wide range of regulated commodities.
- Performed check analyses on violative samples, NDA methods validations, collaborative studies, and National QA samples.
- Reviewed, evaluated and made recommendations regarding the reliability and accuracy of methods used by industry.
- Consulted and advised compliance officers and investigators.
- Monitored compliance programs.
- Evaluated and recommended the purchase of instrumentation systems and equipment.

TRAINING

(Given) Provided on-the-job training to FDA personnel. Made presentations to FDA and industry at local, district, regional, and national meetings and workshops sponsored by FDA and trade/professional organizations.

(Received) Significant courses have involved FDA laws, regulations and policies, investigative/auditing techniques, validation, quality assurance, computer systems, supervision, communications, and self-directed work teams.

FORMAL TEMPORARY ASSIGNMENTS (DETAILS)

- Compliance Officer
- Office of Regulatory Affairs (ORA-21) Staff (Headquarters - Field)
- Consumer Safety Officer (Headquarters - Medical Devices)
- Program Analyst (Headquarters - Foods)
- Supervisory Investigator
- Recall and Emergency Coordinator
- Complaint Coordinator
- Registration Monitor
- Government Wide Quality Assurance Program Coordinator
- Supervisory Chemist
- Laboratory Research Coordinator

AWARDS

- Recognitions for significant contributions in furthering the Agency's partnership goals with the medical device industry including four team Hammer awards from Vice President Gore's National Performance Review.
- FDA Outstanding Achievement Award (1998)
- FDA Group Award of Merit for extraordinary commitment, creativity, and effective development of the criteria necessary for the audit requirements of ORA's Investigator Performance Certification Program (1998).
- CDRH Cash Award for outstanding performance in the development and implementation of the design control aspects of the Quality System Regulation (1998).
- CDRH Cash and Time Off Awards for outstanding contributions made during the Center-wide organizational transformation effort to transform Center processes (1998).
- Other special recognitions include Outstanding Performance Awards, District Honor Roll Membership, FDA Commendable Service Award, Commissioners' Special Citations, FDA Award of Merit (Group), employee suggestion awards, special act and service awards, and various headquarters, regional and district commendations for outstanding work performance and quality, professionalism, competency, training skills, diligence, knowledge, taking charge of situations, use of good judgement, cooperation, altruism, quick grasp of complex issues, conscientiousness, congeniality, and dedication to duty.

AFFILIATIONS

Memberships include ASQ (Biomedical Division), and AFDO.

EDUCATION

BS degree in Chemistry from College Misericordia, Dallas, PA

RESUME

Name: Christine Nelson
Address: Division of Enforcement II
Office of Compliance
Center for Devices and Radiological Health
2094 Gaither Road
Rockville, MD 20850
Phone: 301-594-4611, ext. 134

February 1995 to present: Consumer Safety Officer and Quality Systems Expert for the Office of Compliance
As a Consumer Safety Officer and Quality Systems Expert, I:

- Provide guidance and training to FDA and industry on the Quality System Regulation and the Electronic Records and Electronic Signatures Regulation;
- Participate in implementation of the Mutual Recognition Agreement between the US FDA and the European Union – in particular the auditing part of the MRA;
- Participate in development and implementation of a new approach to inspecting medical device manufacturers, the Quality System Inspection Technique;
- Represent the Center for Devices and Radiological Health (CDRH) and participate in the Global Harmonization Task Force's Study Group 4 – Auditing;
- Participate in the development of a proposed rule on Good Tissue Practices for tissues and cellular-based products with the Center for Biologics Evaluation and Research;
- Represent CDRH and participate in FDA's program for level II certification of device investigators;
- Represent CDRH and participate in FDA's working group to develop guidance and training in the Electronic Records and Electronic Signatures Working Group.

May 1993-February 1995: Acting Branch Chief, OB/GYN and Therapeutic Radiation Branch, Division of Enforcement II, Office of Compliance, CDRH.
As Acting Branch Chief, I:

- supervised employees and reviewed their work, including GMP reviews, Warning Letters, and other regulatory action recommendations;
- and provided guidance and training including GMP guidance.

July 1990 to May 1993: Consumer Safety Officer, Manufacturing Quality Assurance Branch, Division of Compliance Programs, Office of Compliance, CDRH
As a Consumer Safety Officer, I:

- Reviewed establishment inspection reports submitted for foreign device manufacturers and for domestic device manufacturers as part of regulatory actions;
- Identified the appropriate GMP regulatory cites to address GMP objectionable conditions, evaluated supporting documentation for adequacy, and provided an overall evaluation of the state of control and compliance in support of regulatory actions;
- Drafted Warning Letters for foreign firms, and evaluated their replies, and drafted responses letters to them;
- Provided support for three major injunctions including a corporate-wide injunction.

September 1977 - July 1990: Compliance Officer, Office of Compliance and Administrative Litigation, US Consumer Product Safety Commission.
As Compliance Officer I:

- Provided advice, guidance and training to CPSC and industry on product safety regulations;
- Provided support for legal actions including seizures and injunctions;
- Developed and monitored compliance programs.

December 1975 – September 1977: Public Health Analyst, Office of Epidemiology, US Consumer Product Safety Commission.
As Publish Health Analyst, I:

- Analyzed injury and death data to identify hazard patterns associated with consumer products.

June 1974 – December 1975: Consumer Safety Officer, New Orleans Area Office, US Consumer Product Safety Commission.
As Consumer Safety Officer, I:

- Inspected manufacturers, distributors and retailers to check compliance with CPSC regulations for consumer products;
- Investigated accidents, injuries and deaths to explore the role of consumer products in the incidents.

Education:
Northern Illinois University, DeKalb, IL – Bachelor of Science
University of Illinois, Champaign/Urbana, IL – Master of Science

Memberships:

- Association for the Advancement of Medical Instrumentation (AAMI)
- American Society for Quality (ASQ)

Achievements and Awards:

- American Society for Quality Certified Quality Auditor
- Recognition of Technical Assistance to Israel for which FDA received the Ronald H. Brown Award, 1996
- FDA Commendable Service Award, 1997
- CDRH Special Recognition Awards, 1995, 1996, 1997, 1998
- FDA Group Recognition Awards, 1994, 1995, 1998
- CDRH Employee of the Month, 1997

Robert G. Ruff, CSO
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EDUCATION AND TRAINING:

B.S., Biology, June 1983
Lincoln Memorial University, Harrogate, TN

- Alpha Chi National Honor Society
- Dean's List

Completed or instructed at FDA and industry sponsored national and regional training, including:

- Six Month Basic Investigators' Training
- Basic Food & Drug Law and Evidence Development
- The Reid Technique of Specialized Interviewing
- Introduction to Medical Devices
- Intermediate Medical Devices Plastics
- Medical Device Process Validation (faculty)
- Industrial Sterilization for Drugs and Devices
- Computer System Validation
- Introduction to International Inspections
- Sterilization Issues for Medical Device Inspections (Regional)
- Medical Device Electronics (Regional)
- Medical Device Plastics (faculty, Regional)
- Quality Audits for Improved Performance (ASQC)

CERTIFICATION:

Level II Certified Medical Device Investigator and Performance Auditor

QUALIFICATIONS AND EXPERIENCE:

- Six years of Medical Device Industry Experience
- Eight years experience with FDA (currently, GS-13/4 Medical Device Specialist)
- Eight foreign inspection campaigns to date (outcomes from NN to AA, W/L w/Auto Detention)
- Member, Medical Device Certification Audit Development Cadre
- Member, Design Control Inspectional Strategy Team
- Member, CDRH Reengineering Team (Reengineering the Medical Device Inspectional Process)
- Faculty Member, AAMI "GMP Requirements and Industry Practice" (Quality System Course)
- Faculty Member, AAMI "Design Control Requirements and Industry Practice"
- Faculty Member, National Course on Medical Device Process Validation
- Faculty Member, Technical Advisor to Central Region Training Branch (Medical Device Training)
- New Jersey District Medical Device Cadre Facilitator
- Recruited to provide technical and investigational support to OCI NYFO
- Presented at local, national and international medical device conferences, workshops, etc.
- Conducted numerous, technical medical device inspections and investigations
- Conducted Pre-op reviews and SBR site visit
- Completed details as Acting Compliance Officer and Acting Supervisory Consumer Safety Officer
- FDA Award of Merit, FDA Outstanding Achievement Award, numerous letters of Commendation and Appreciation

Kimberly A. Trautman draws on her experience with FDA as the Center for Devices and Radiological Health (CDRH) expert on Good Manufacturing Practices (GMPs) and Quality Systems. In addition to writing the 1996 final rule and the 1995 working draft of the quality system regulation and preamble, she also reviews inspection reports of foreign and domestic medical device manufacturers to identify violations of the GMP regulations and provides guidance to FDA field investigators and the medical device industry. She is a member of the Global Harmonization Task Force, is a representative to the U.S. Technical Advisory Group (TAG) to ISO/TC 176 and ASQC Z-1/TG 11 Quality Assurance Committee, is the U.S. delegate to ISO/TC 210, and is the ISO TAG to TC 210 Working Group 1 Co-chair.

Trautman has taught at medical device training courses and prior to her current position was a patent examiner specializing in medical devices. She received an MS degree in biomedical engineering from the University of Virginia and a BS degree in molecular and cell biology from the Pennsylvania State University. She is a member of ASQC and the Association for the Advancement of Medical Instrumentation.

Record to the File – Employee Experience Record Date: 2/17/99

Employee: Corinne Tylka
Consumer Safety Officer, GS-13/7

Office: Office of Compliance, DOEI/GSDB
Center for Devices & Radiological Health
2098 Gaither Rd. (HFZ-323)
Rockville, MD 20850

Phone: 301-594-4595, ext. 170

Education: Bachelor of Science degree in physics, Penn State 1974-1977

Employment: 1977-1981 – FDA Bureau of Radiological Health, physicist GS-5

Work description: lab instrumentation, noncoherent light source and laser measurements, instrument calibrations in support of FDA/BRH field laser inspection programs

1981-1984 – housewife, unemployed in Hamburg, Germany

1984-1993– FDA/CDRH Office of Compliance, Div. of Electronic Products

Work description: Consumer Safety Officer - regulation of medical and nonmedical laser manufacturers under the Federal laser product performance standard. Report reviews, 5-10 laser manufacturer inspections per year.

On-the-job training: Grad. Courses at U. MD: Optics, Quantum Mechanics, Complex Variables
Basic Food, Drug, & Law course
Medical Device Updates
Radiation Physics Course, Boston 1987
Numerous in-house computer training courses

1993-present – FDA/CDRH Office of Compliance, Div. Of Enforcement I, General Surgery Devices Branch

Work description: Consumer Safety Officer - regulation of medical laser manufacturers under the Federal laser product performance standard via Laser Product Report reviews, communication with industry. In addition, reviews of GMP and quality systems inspections, 510(k)s, IDEs, PMAs, device labeling issues, recalls, legal actions

Training: Numerous in-house Office-wide GMP training, Quality Systems reg., Design Controls, Med. device software safety
Numerous in-house computer training courses

Conference-American Society of Lasers in Medicine & Surgery
(Toronto) 1994
IEC 601 training 1996
AAMI GMP Requirements & Industry Practice 1997
Electromagnetic Compatibility/Electromagnetic Interference 1997
CDRH - Medical Device Polymers 1998
CDRH – Medical Device Biomaterials 1998

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EXPERIENCE

Team Leader, Quality Systems Inspection Reengineering Team, FDA, Center for Devices and Radiological Health (CDRH)	1997-1999
Chief, Ob-Gyn, Gastroenterology and Urology Device Branch, Division of Enforcement II, Office of Compliance, FDA, CDRH	1990-1993
Chief, Product Evaluation Branch II, (MDR group) Division of Product Surveillance Office of Compliance & Surveillance, FDA, CDRH	1990-1993
Executive Development Program, Office of Personnel Management, Washington, DC, temporary positions included Acting Director of Investigations, Baltimore District, FDA Commissioner's Executive Office staff, FDA Office of International Affairs, and others	1989-1990
Consumer Safety Officer, Import Operations Branch, Division of Field Investigations, Office of Regional Operations, Office of Regulatory Affairs (ORA) FDA, Rockville, MD	1987-1989
FDA Regional Small Business Representative, Atlanta Region, ORA, Atlanta, GA	1981-1987
FDA Field Investigator, Waukegan Resident Post, Chicago District, ORA, Waukegan, IL	1977-1981
FDA Field Investigator, Chicago District Office, ORA, Chicago, IL	1976-1977

ACOMPLISHMENTS RELATED TO QUALITY SYSTEM REENGINEERING

As Team Leader, Quality Systems Inspection Reengineering Team, CDRH, I have managed all aspects of the reengineering effort. Some of the activities include benchmarking, evaluating the present program, making change proposals and implementing all aspects of the proposal. I manage at least seven sub-teams consisting of quality system experts and professionals with expertise in enforcement, inspections, and other areas. Sub-team projects include the creation of the QSIT Handbook, development of a new Compliance Program for quality systems inspections, development of a training course for field investigators covering the new inspection technique, managing a pilot inspection program, which involves three districts, managing an evaluation program, managing a web site, handling interactions with field management, reengineering steering committee, CDRH management, industry, the public and the media.

As Chief, Ob-Gyn, Gastroenterology and Urology Device Branch, Division of Enforcement II, CDRH, I am responsible for all aspects of enforcement that involve firms in this product area, (which includes such products as condoms and dialysis devices). I am involved in both issuances of assignments to inspect foreign and domestic device firms, and the review of the findings from inspections, as well as other legal matters. I oversee review of all violative foreign inspection reports that fall in this product area, and develop and issue warning letters and other correspondence related to those inspections. I also manage domestic legal actions, such as injunctions, related to quality system violations that involve firms in this product area, and consult with district officials on issues related to quality system inspections. I managed the Center's largest corporate wide injunction project involving quality system violations.

As Chief, Product Evaluation Branch II, Division of Product Surveillance, CDRH, I contributed some content material to the Quality System Regulation, when it was being drafted in 1993. As chief of one of the two MDR branches, I frequently issued assignments to district offices covering device problems, and supervised numerous activities related to device problems. I was involved in follow-up activities related to device problems, such as recalls, press releases, device testing, and coordination with other agencies.

As Acting Director of Investigations in Baltimore District, I was responsible for all investigation and inspection in the three-state area. During my tenure I supervised several aspects of the generic drug investigations; an action that eventually resulted in large fines and jail time for corporate individuals.

As Consumer Safety Officer, Import Operations Branch, Division of Field Investigations, I was responsible for numerous aspects of the national import program. Specifically, I managed the training courses for all FDA's import inspectors and managers, as well as national import conferences.

As Small Business Representative, Atlanta Region, I was involved in providing technical assistance to firms regulated by FDA. The assistance included on-site visits, phone assistance, providing references and copies of regulations and other technical information. I developed and participated in industry workshops, primarily for the medical device industry, but also for other industries, in the eight state geographic area that comprises the southeast region. I developed much of the course content and technical material that was incorporated into DSMA's (CDRH Division of Small Manufacturers Assistance) national workshops on Good Manufacturing Practices.

As Field Investigator, Chicago District Office and Waukegan Resident Post I was involved in inspecting manufacturers, distributors, and other establishments for compliance with medical

device, drug, biologic, food and veterinary medicine requirements. During my tenure at Waukegan I was involved with inspecting some of the nation's largest pharmaceutical and device manufacturers.

OTHER ACCOMPLISHMENTS

Served formal details as Acting Deputy Director, Office of Compliance, CDRH; Acting Director Division of Product Surveillance, CDRH; Acting Deputy Director, Pacific Region.

Managed large projects, such as Commissioner Young's Action Plan II (Import Program Initiatives); spearheaded the Center Director's (Benson) Listening Group Project.

Worked on agency wide groups: was CDRH representative to FDA's Customer Service Initiative Group; represented CDRH at FDA's Compliance Policy Council.

Oversaw projects such as development of the MDR, Distributor Reporting and User Facility reporting regulation, implementation of new data systems for compilation & analysis of device problem reports, and implementation of numerous action items from the CDRH Action Plan, specifically those related to post market surveillance. Developed a new automated method to handle MDR reviews.

Was involved in the European Community (EC-1992) project in International Affairs Staff, as Acting Health Science Administrator. I prepared briefings for the Vice President, the Associate Commissioner for Health Affairs and Center Directors.

Was involved in preparing the agency's FY-90 and FY-91 budgets, as Budget Analyst in the Division of Financial Management. I helped prepare the Commissioner's testimony for the House and Senate Appropriations hearings, and briefings for the commissioner and center directors.

EDUCATION

Bachelor's Degree: Life Sciences – University of Wisconsin – Parkside, Kenosha, WI
Numerous FDA Courses involving medical devices, process validation, law, and compliance

PROFESSIONAL AFFILIATIONS

American Society for Quality, Biomedical Division and Quality Audit Division

NORMAN WONG

Norm is an Engineer and National Medical Device Expert attached to DEIO (Division of Emergency & Investigational Operations) working out of the Seattle District Office. He started working for the Agency in 1972 and in 1983 became a national expert. He has over twenty years of specialized experience in performing domestic and foreign medical device inspections. He is highly experienced in inspecting medical device manufacturing processes and medical device electronics. He serves as a technical consultant for the field operations and the Centers for Devices and Radiological Health. He also, occasionally serves as a technical consultant for the Centers for Biologics and Drugs.

He serves on the course advisory groups and is a principle instructor in basic and advance medical device courses relating to manufacturing processes, computer inspectional applications, and medical device electronics. He has provided training to Agency and outside the Agency throughout the country.

He is currently participating in CDRH reengineering projects relating to new inspectional techniques (QSIT, HACCP and DCIS), compliance action levels, and computerized training techniques. He is a member of the device certification development cadre, a performance auditor, and a member of the foreign inspection team. He is also participating in revising the ORA medical device inspectional guidance document and a number of IOM updating projects.

Norm has a BS degree in chemical engineering and years of formal and informal studies in electronics and computer software related subject areas.

ALLEN WYNN

Allen Wynn is a Consumer Safety Officer (CSO) in the Field Programs Branch (FPB), Division of Programs Operations, Office of Compliance, Center for Devices and Radiological Health (CDRH). Mr. Wynn has been with FPB since May 1993 and his responsibilities include, but not limited to, oversight of the Premarket Approval, Foreign, and Class III 510(k) Pre-Clearance programs.

Mr. Wynn has been with CDRH since May 1990, where he worked as a Good Manufacturing Practice (GMP) reviewer with the former Manufacturing Quality Assurance Branch. Responsibilities included reviewing field inspectional reports of both domestic and foreign medical device manufacturers to determine whether violations of the GMP had occurred. In addition, duties and responsibilities also included the review of Premarket Approval Applications and responding to written and verbal inquires from industry and the FDA field on the interpretation and application of GMP requirements to the manufacture of medical devices.

Mr. Wynn joined FDA in September 1977 as a CSO with the New York District Office.

Mr. Wynn has a Bachelor of Science degree in Chemistry from Elizabeth City State University, Elizabeth City, NC.

Scheduled Members and Guests of the January 21-22, 1998 Meeting of the Ad Hoc Group for Quality System Inspections

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Ad Hoc Group for Quality Systen

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Printed: 1/20/98

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Quality System Inspection Technique (QSIT) Development History

August 13 – 14, 1997: QSCA Development Workshop to explore HACCP for the inspection of Medical Device Manufacturers (meeting which stimulated the development of QSIT and HACCP for Medical Devices Development Projects)

January 21 – 22, 1998: FDA QSIT Development Team members participated as invited guests of FDLI Ad Hoc Group for Quality System Inspections

April 16 – 17, 1998: FDA QSIT Development Team members participated as invited guests of FDLI Ad Hoc Group for Quality System Inspections

May 4, 1998: FDA QSIT Development Team meeting

June 18, 1998: Quality System Inspections Open Public Meeting, comments used to revise QSIT

August 1998: Proposed QSIT provided to non-development team Novice, Intermediate and Expert Medical Device investigator's for review and comment, comments used to revise QSIT

August 17 – 21, 1998: FDA QSIT Development Team meeting

September 1998 – February 1999: QSIT Field Tested by three FDA districts, monthly phone calls on progress, test cadre input used to revise QSIT

December 7, 1998: FDA QSIT Development Team members participated as invited guests of FDLI Ad Hoc Group for Quality System Inspections

January 14, 1999: FDA QSIT Development Team members participated as invited guests of FDLI Ad Hoc Group for Quality System Inspections

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
G2B (Activity3)	Increase the focus of the approach to conducting Quality System inspections on the key elements of the major subsystems of the Quality System with linkages to the remaining subsystems.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	Responses by investigators to a question on an Evaluation Form
Scope and nature of the process to be followed.[2]	During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections. Investigators will provide input into evaluating the QSIT by completing an Evaluation Form for each QSIT inspection conducted during the Study. The effect of the use of QSIT in increasing inspectional focus will be determined by the following Evaluation Form question: "Did use of the QSIT result in a more focused inspection? Yes __ No __ Comments _____ ..." Responses will be tabulated and analyzed. Overall responsibility for this activity: G. Layloff (HFR-SW450) and T. Wells (HFZ-332)	
Acceptance criteria (if known)	The majority of responses affirm that the use of QSIT resulted in a more focused inspection.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**	This activity provides a direct measurement on whether use of the QSIT approach resulted in a more focused inspection.	
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.	This pre-deployment activity allows investigators (internal stakeholders) to provide input into the assessment of this goal.	

Rev.12/18/98

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
G2B	Increase the focus of the approach to conducting Quality System inspections on the key elements of the major subsystems of the Quality System with linkages to the remaining subsystems.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
3	Test	Responses by investigators to a question on an Evaluation Form
Acceptance Criteria	The majority of responses affirm that the use of QSIT resulted in a more focused inspection.	
Summary of Results	The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. The investigators provided input into evaluating the QSIT by completing an Evaluation Form for QSIT inspections conducted during the Study. The investigator's input into the assessment of this goal was obtained through responses to the Evaluation Form question: "Did use of the QSIT result in a more focused inspection? Yes __ No __ Comments___..." A total of 42 QSIT inspections were conducted during the Study. An Evaluation Form was submitted for each inspection. A tabulation of individual responses is attached. Responses to the question were as follows: Yes 37 (88%) No 1 (2%) Other 4 (10%) *(3 responses were – both Yes and No and 1 response was - Not sure)*	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments		
Activity Champion(s)	Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332)	

Rev. 2/12/99

Item # G2B (Activity 3)

INVESTIGATOR QSIT EVALUATION FORM question:

Did use of the QSIT result in a more focused inspection? Yes __ NO __ Comments ____

TABULATION of RESPONSES

Inspection Code	Yes	No	Other	Comment	*
1A1	X			Yes – a different type of focus	B
1A2	X			More focused in these 4 areas.	B
1A3	X				B
1A4	X				B
1B1	X			However, I would have dug deeper in this firm if I wasn't following QSIT.	B
1B2	X			It gave me a very directed approach & made me focus on certain process & not try to cover them all.	B
1B3	X			I was very focused on the areas I reviewed.	B
1C1	X			I think I was more focused on the four subsystems. During a regular inspection, I follow the violations to wherever it leads. I usually end up conducting a very thorough inspection. I do not feel like I have conducted a very thorough inspection using the QSIT technique. It may just take a little time to get used to using this method and I may very well may have conducted a very thorough inspection. I feel more comfortable with conducting a thorough inspection using the bottom up approach.	A
1C2	X			I am not sure how long this inspection would have taken if conducted using the regular method of inspection. I'm sure it would have taken longer, but most likely with the same result.	A
1C3	X			I find that when I use the traditional method of inspection, I find more deficiencies, because I look at more of everything (SOPs, DHRs, etc.) With QSIT, I still find deficiencies, but not as much as I would using the traditional method.	A
1C4	X			I'm not sure if a focused inspection was the right type of inspection to perform for this firm. I think I would have found more deviations if I had performed a regular type of inspection. I found that I was fighting to keep to the agenda. I wanted to deviate from QSIT to follow suspected problems. If I had more time to conduct this inspection, I would have followed moew leads and I'm sure, I would have found more deviations. I think the corrective and preventative action subsystem was cheated by utilizing this subsystem. I just needed more time to adequately cover this subsystem.	A
1D1	X			I still struggled with knowing when to say when and fought the urge to do more. I also found a little rushed at times, and believe I could have done a better job preparing the 483.	C
1D2	X			This is especially true of the management responsibility section.	C
1D3	X				C
1D4	X				C
2A1		X		It is difficult to see the difference in this inspection. Firm did not have many of the required procedures.	A

Inspection Code	Yes	No	Other	Comment	*
2B1			Yes and No	QSIT tools helped to focus on and complete all aspects of the QSIT requirements. Following the prescriptive requirements of QSIT, while systematic, was sometimes contrary to the natural flow of this inspection. Resulted in a need to track multiple open issues and return to them later–this caused some re-review	C
2B2	X			In part, particularly in getting started and for general review but was less useful in areas when problems were encountered.	C
2B3	X			It does define a focus, but the sequence of review does not always fit the natural flow.	C
2C1	X			The format of the handbook kept the inspection focused.	C
2C2	X			I stayed with the QSIT booklet format.	C
2C3	X			QSIT Handbook was the most useful – it helps structure the course of the inspection.	C
2C4	X				C
2D1			Yes and No	Yes – more focused on systems & written procedures No – less focused on implementation of procedures	B
2D2	X			On systems, less focus on products/issues	B
2D3			Yes and No	Time & systems – Yes; Product problems – No	B
2D4	X			On systems (Less focused on products & performance)	B
3A1	X				C
3A2	X				C
3A3	X				C
3A4	X			Firm's representative knew exactly where the inspection was going and for the most part, was able to gather requested documents/information on personnel available for the next section. They all had a copy of the QSIT handbook (e.g. covering design controls).	C
3B1	X			This was a PMA inspection where no PMA device has been manufactured for commercial distribution. The EI's emphasis was on their various procedures and on all the validations performed. As such I was not able to utilize the QSIT system to its fullest capabilities. However, the use of the QSIT system enabled a dynamic operative system to control the focus. During the EI, it was also used to perform an artificial inspection to determine how it would assist me if a non-PMA EI was being performed.	C
3B2	X			Especially more focused under Management Controls & CAPA.	C
3B3	X			Objectionable condition coverage was focused without expanding more time in reviewing records beyond the number of records chosen for review.	C
3B4	X			Definitely. Each subsystem was covered thoroughly in a reasonable amount of time for the firm being inspected.	C
3C1	X				B
3C2	X				B
3C3	X				B
3C4	X				B
3D1			Not sure		A
3D2	X				A
3D3	X				A
Total	37	1	4		

* Time in position as investigator, where A = 1-5 years, B = 6-10 years, and C >10 years

G3

Harmonize

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
G3 (Activity 1)	More closely harmonize the inspection technique for conducting Quality System inspections with that used in the international community.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	Industry responses to a multi-part question on a Customer Satisfaction Survey
Scope and nature of the process to be followed.[2]	During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections. The most responsible person at each of the inspected firms who was directly involved in the inspection will be mailed an OMB approved Customer Satisfaction Survey. They will be invited to voluntarily provide their views on the QSIT by completing and returning the survey form. The survey form will contain the multi-part question, "We designed QSIT to be closer to the Global Harmonization Guideline for Auditing Quality Systems. Did you find the QSIT approach similar to that used by auditing organizations utilized by your firm (i.e. Notified Bodies, third party assessors, internal auditing groups etc.)? Yes [ ] No [ ] No opinion or experience with this subject [ ] If yes, was this useful to your firm? Yes [ ] No [ ] Explain and provide examples of the similarities and usefulness." Responses will be tabulated and analyzed. Overall responsibility for this activity: G. Layloff (HFR-SW450) and T. Wells (HFZ-332)	
Acceptance criteria (if known)	The majority of survey responses affirm that the QSIT approach is similar to that used by other auditing organizations. Also, the majority of survey responses affirm that having a similar approach is useful to firms.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**	This activity provides a direct and objective measurement on whether the QSIT approach is similar to that used by other auditing organizations. It does not directly compare QSIT to the current FDA auditing technique.	
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.	This pre-deployment activity allows firms (stakeholders) to provide input into the assessment of this goal.	

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
G3	Increase the focus of the approach to conducting Quality System inspections on the key elements of the major subsystems of the Quality System with linkages to the remaining subsystems.	
Activity #	**Type of activity** (test or analysis)	**Parameter(s)** to be measured
1	Test	Industry responses to a multi-part question on a Customer Satisfaction Survey
Acceptance Criteria	The majority of survey responses affirm that the QSIT approach is similar to that used by other auditing organizations. Also, the majority of survey responses affirm that having a similar approach is useful to firms.	
Summary of Results	The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. A total of 42 inspections were conducted during the Study. Subsequent to the conclusion of the inspection, the most responsible person at each of the 42 inspected firms who was directly involved in the inspection was mailed an OMB approved Customer Satisfaction Survey. They were invited to voluntarily provide their views on the QSIT by completing and returning the survey form. The survey form contained the multi-part question: " We designed QSIT to be closer to the Global Harmonization Guideline for Auditing Quality Systems. Did you find the QSIT approach similar to that used by auditing organizations utilized by your firm (i.e. Notified Bodies, third party assessors, internal auditing groups etc.)? Yes [ ] No [ ] No opinion or experience with this subject [ ] If yes, was this useful to your firm? Yes [ ] No [ ] Explain and provide examples of the similarities and usefulness." A total of 19 (45%) industry responses were received. A tabulation of individual responses is attached. It was determined that 14 of the 19 firms found the QSIT approach similar to that used by auditing organizations they utilized. *(4 of the 19 responding firms had no opinion or experience with the subject, and 1 did not provide a specific answer. None of the firms stated the QSIT approach was not similar).* A total of 12 of those 14 firms stated the similar approach was useful. *(2 did not provide a specific answer. None of the firms stated the similar approach was not useful.)*	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments		
Activity Champion(s)	Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332)	

Item # G3 (Activity 1)

QUALITY SYSTEM INSPECTION TECHNIQUE (QSIT) CUSTOMER SATISFACTION SURVEY question:

Part 1 We designed QSIT to be closer to the Global Harmonization Guideline for Auditing Quality Systems. Did you find the QSIT approach similar to that used by auditing organizations utilized by your firm (i.e. Notified Bodies, third party assessors, internal auditing groups etc.)? Yes [ ] No [ ] No Opinion or Experience with this subject [ ]

Part 2 If yes, was this useful to your firm? Yes [ ] No [ ]

Part 3 Explain and provide examples of the similarities and usefulness.

TABULATION of RESPONSES

PART 1				PART 2		PART 3
Form	Y	N	?	Y	N	Comment
1	X			X		Our Quality System is structured per the 20 sections of ISO 9001. We are not ISO 9001 certified as yet, but auditors that we have used performed audits very similar to the QSIT format – consistency.
2	X			X		Reduces confusion in establishing & maintaining the quality system
3	X			X		We are ISO 9001 certified. Allows us to standardize our approach to all processes and achieve full compliance for both ISO and the QSR.
4	X					I found the QSIT to be very similar to NB approach (e.g., Management Controls). Because of this similarity, it seems like the FDA could have used results from a NB to satisfy regular facility inspections.
5			X			
6						I preferred the FDA's approach to that taken by our ISO registrar. FDA was more process-oriented. Our ISO registrar spends a lot of time searching for minor mistakes in paperwork and asking for trivial changes to the QA manual & other documents.
7	X			X		Consistency in auditing style and approach.
8	X					We are a ISO 9001 company and our quality manual adapts very well with the QSIT.
9	X			X		Very similar to approach taken by third party assessors and our customers. This facilitates the audit process.
10			X			
11	X			X		The 4 areas targeted by QSIT closely parallel areas Notified Bodies target. Doc. is set up to easily highlight these areas and facilitates ease of communication.
12			X			
13	X			X		FDA spend time learning how systems work (not necessarily verifying the integrity of systems (or how they work) – Approach by FDA was similar to TUV.
14	X			X		Our external auditor that conducts an annual audit, used the QSIT approach. This helped us prepare for the FDA Audit format.
15			X			

PART 1				PART 2		
Form	Y	N	*	Y	N	Comment
16	X			X		Where the areas of the inspection were similar the expected results or perceived level of compliance was different. Other organizations audit to a level of determining whether procedures are in place. The FDA appears to audit compliance to a procedure.
17	X			X		Starting with Management review and starting each section with an overview of systems – both provided our staff with a familiar auditing process.
18	X			X		It makes it much easier to explain our quality system to the auditors/inspectors when there is a common focus.
19	X			X		The top down approach was similar to our Notified Body approach to auditing. The main difference between our last FDA inspection and our Notified body assessment is the amount of time out on the manufacturing floor. Out notified body spends more time looking at how systems work and the FDA inspector we had looked for documentation supporting the various systems, both valid approaches but still slightly different.

*No Opinion or Experience with this subject

TOTALS

Did you find the QSIT approach similar to that used by auditing organizations utilized by your firm (i.e. Notified Bodies, third party assessors, internal auditing groups etc.)?

Yes 14 No 0 No Opinion or Experience with this subject 4 (No response 1)

└──►If yes, was this useful to your firm?

Yes 12 No 0 (No response 2)

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
G3 (Activity 2)	More closely harmonize the inspection technique for conducting Quality System inspections with that used in the international community.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Comparison Analysis	QSIT compared to ISO Audits
Scope and nature of the process to be followed.[2]	Study will require co-operation of 3 - 4 notified bodies and at least 2 Competent Authorities. They will be asked to review QSIT format and give an analysis of how it compares with ISO audits. Use contacts from GHTF/SG-4 to approach notified bodies and competent authorities. Suggested notified bodies: TUV, BSI, Australia, Underwriters Laboratory (USA or UK); Suggested Competent Authorities: Medical Devices Agency (great Britain) and National Standards Authority of Ireland. A comparison worksheet document will be developed for use from the QSIT flowcharts. Proposed timeline for activities: Contact to solicit participants: By 2/16/99 Proposed initiation date: 3/5/99 (Ship QSIT materials and worksheets to participants) Proposed worksheet return dates: 4/23/99 Proposed completion date: 6/4/99 Responsibility for activity: Karen Coleman (HFR-SE150); CDRH/Tim Wells provide copies of QSIT Handbook, Federal Express Acct. Info: Chris Nelson and Georgia Layloff review and guidance ;	
Acceptance criteria (if known)		
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**	Strengths: Identify similar areas that are harmonized Weakness: Differences may surface that cannot be harmonized and must be covered separately for FDA t meet their obligation under the law.	
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.	Technique allows analysis of inspectional techniques with minimum expenditure of time and money.	

Rev.12/18/98

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome

QSIT Validation Activity Report

Item G3
Activity 2

This Activity was not completed.

MANAGEMENT CONTROL WORKSHEET

1. YES NO Does the auditor confirm that a quality policy, management review, quality audit procedures, quality plan and quality system procedures, and instructions have been defined and documented?

   1.1 Where are the reviews conducted? [select one of the following and write in the comment section below:] (1) Auditor's office; (2) At firm during the audit; (3) Both places

	Prior to Audit (check all that apply)	During the Audit	Comments:
Quality Policy			
Management Review			
Quality Plan			
Quality System Procedures			

2. YES NO Does the auditor confirm a quality policy has been implemented?

   2.1 How was this confirmed? Review of procedures Interview/s with employees Procedure reviews & Interviews; Other_____

3. YES NO Does the auditor review the firm's established organizational structure to confirm that it includes provisions for responsibilities, authorities, and necessary resources?

4. YES NO Does the auditor confirm that a management representative has been appointed.?

   4.1 Describe how the auditor evaluates the purview (authority) of the management representative?

5. YES NO Does the auditor confirm that management reviews include a review of the suitability and effectiveness of the quality system are being conducted?

   5.1 How was this confirmed? Review of procedures Interview/s with employees Procedure reviews & Interviews; Other_____

6. YES NO Does the auditor confirm that quality audits, including reaudits of deficient matters, of the quality system are being conducted.

   6.1 How was this confirmed? Review of procedures Interview/s with employees Procedure reviews & Interviews; Other_____

DESIGN CONTROL WORKSHEET

1. YES NO Would an auditor routinely select a single design project for review?

   1.1 If "NO" explain what your organization would do and why.

2. YES NO For the design project selected, does the auditor determine whether the auditee has design control procedures (addressing the requirements of ISO 9001 section 4.4) that have been defined and documented?

3. YES NO Does the auditor assure design & development planning activities include assigned responsibilities and interfaces.

4. YES NO Does the auditor evaluate the firm's conduct of risk analysis while proceeding through the assessment of the firm's Design Control system.

   4.1 If "NO" explain how your organization would evaluate risk analysis and why.

5. YES NO Does the auditor confirm that design inputs were established?

6. YES NO Does the auditor assure that design outputs that are essential for the proper functioning of the device are identified?

7. YES NO Does the auditor confirm that acceptance criteria are established prior to the performance of verification and validation activities?

8. YES NO Does the auditor review design verification activities to confirm that design outputs meet the design input requirements?

9. YES NO Does the auditor have to confirm that design validation data shows the approved design met the predetermined user needs and intended uses?

   9.1 If "YES" describe how this confirmation is made.

10. YES NO Does the review of the completed design validation assure the firm did not leave any unresolved discrepancies.

11. YES NO If the device contains software, does the auditor confirm that the software was validated?

12. YES NO Determine if design validation was accomplished using initial production devices or their equivalents?

13. YES NO Does the auditor confirm that changes were controlled including validation or where appropriate verified?

14. YES NO Does the auditor determine if design reviews were conducted?

14.1 If "YES" how were the reviews confirmed? Review of Procedures/Records
Interview/s with employees Procedure/records reviews & Interviews
Other_____

15. YES NO Does the auditor determine if the design was correctly transferred to production?

Corrective and Preventive Actions Worksheet
(CAPA)

1. How do auditors confirm that the CAPA system procedure(s) for the requirements of ISO 9001 section 4.14 have been defined and documented?

   Review of procedures Interview/s with employees Procedure reviews & Interviews

   Other _____

2. How does an auditor determine if appropriate sources of product and quality problems have been identified?

   Review of procedures Interview/s with employee's Procedure reviews & Interviews

   Other _____

3. YES NO Does the auditor confirm that data from these sources are analyzed to identify existing product and quality problems that may require corrective action?

4. YES NO If sources of product and quality information show unfavorable trends have been identified does the auditor confirm that data from these sources are analyzed to identify potential product and quality problems that may require preventive action?

   4.1 How does the auditor confirm that both corrective and preventative actions were performed?

5. YES NO Does the auditor challenge the quality data information system?

   5.1 Explain "how" the challenge was performed?

6. YES NO Does the auditor determine that the data received by the CAPA system are complete, accurate, and timely?

   6.1 How was the determination performed?

7. How does the auditor confirm that appropriate statistical methods are employed (where necessary) to detect recurring quality problems? [Other than check that there is a written procedure stating appropriate statistical methods will be used]

8. YES NO Does the auditor determine if results of analyses are compared across different data sources to identify and develop the extent of product and quality problems?

   If "No" why is this not done?

9. How does the auditor determine if failure investigation procedures are followed?

   Review of procedures Interview/s with employee's Procedure reviews & Interviews

   Other _____

10. How does an auditor determine if the degree to which a quality problem or non-conforming product is investigated is commensurate with the significance and risk of the non-conformity?

11. YES NO Does the auditor confirm that failure investigations were conducted to determine root cause (where possible)?

12. YES NO Does the auditor confirm that there is a control mechanism for preventing distribution of non-conforming product?

13. YES NO Does the auditor determine if appropriate actions have been taken for significant product and quality problems identified from data sources?

13.1 How is this determination made?

14 . YES NO Does the auditor determine if corrective and preventive actions were effective and verified or validated prior to implementation?

15. YES NO Does the auditor confirm that the firms' corrective and preventive actions did not adversely affect the finished device?

16. YES NO Does the auditor determine that corrective and preventive actions for product and quality problems were implemented and documented?

16.1 How is this verified? Review of procedure Interview/s with employees

Procedure reviews & Interviews; Other_____

17. YES NO Does the auditor determine if information regarding nonconforming product and quality problems and corrective and preventive actions has been properly disseminated, including dissemination for management review?

17.1 How is this determined? Review of procedures Interview/s with employees

Procedure reviews & Interviews: Other_____

Production and Process Controls Worksheet

1. QSIT instructs an investigator/auditor to evaluate production and process controls using the items in a list below.

Select a process for review based on: [If your auditor uses this item place a check mark (√) in the block to the right]

a. CAPA indicators of process problems;

b. Use of the process for manufacturing higher risk devices;

c. Degree of risk of the process to cause device failures;

d. The firm's lack of familiarity and experience with the process;

e. Use of the process in manufacturing multiple devices;

f. Variety in process technologies and product types;

g. Processes not covered during previous inspections;

h. Any other appropriate criterion as dictated by the assignment;

2. YES NO Does your system provide guidance on how to select a process for review?

3. YES NO Is the guidance similar to the QSIT guidance?

3.1 If "NO" explain in written text how an auditor makes this type of decision and what would be significant to your organization for guidance on covering this system?

4. YES NO Does the auditor review the specific procedure(s) for the manufacturing process selected and the methods for controlling and monitoring the process?

4.1 How does the auditor confirm that the process is controlled and monitored?

Data review Interview/s with employee's Data reviews & Interviews

Other _____

Note: Control and monitoring procedures may include in-process and/or finished device acceptance activities as well as environmental and contamination control measures.

5. YES NO If during the auditor's review of the Device History Records (including process control and monitoring records, etc.) they find the process is outside the firm's tolerance for operating parameters and/or rejects or that product nonconformances exist would they evaluate it?

Would the evaluation include any of the following?

5.1. YES NO Determining whether any nonconformances were handled appropriately?

5.2. YES NO Evaluating the validation study in full to determine whether the process has been adequately validated?

5.3. YES NO If the results of the process reviewed can not be fully verified, would the auditor confirm that the process was validated by reviewing the validation study?

5.4. YES NO If the process is software controlled, will the auditor confirm that the software was validated ?

5.5. YES NO Does the auditor routinely review and evaluate the software validation study?

5.6 Other _____

6. YES NO Does the auditor confirm that personnel have been appropriately qualified to implement validated processes or appropriately trained to implement processes which yield results that can be fully verified?

Sterilization Process Controls Worksheet

1. YES NO Does the auditor confirm that the sterilization process was validated by reviewing the validation study. If "NO" explain why this is not done.

2. YES NO Does the auditor review the specific procedure(s) for the sterilization process selected and the methods for controlling and monitoring the process

   2.1 How does the auditor confirm that the process is controlled and monitored?

   [check all that apply] Review of procedures Interview/s with employees

   Review of processing records Other_____

3. If review of the records (including process control and monitoring records, acceptance activity records, etc.) reveals that the sterilization process is outside the firm's tolerance for operating or performance parameters:

   3.1 YES NO Does the auditor determine whether the nonconformances were handled appropriately?; and

   3.2 YES NO Does the auditor review the equipment adjustment, calibration, and maintenance?

4. YES NO If the sterilization process is software controlled does the auditor confirm that the software was validated?

5. YES NO Does the auditor confirm that personnel have been appropriately qualified and trained to implement the sterilization process?

   5.1 How was this confirmed? [Check all that apply] Review of procedures

   Interview/s with employees Training record reviews

   Other_____

G4

Quality System Regulation Coverage

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
G4 (Activity 1)	Provide broad and adequate coverage of the Quality System Regulation when conducting a comprehensive Quality System inspection.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Analysis	QSIT Inspectional Objectives and narrative "linkages" described within the "QSIT Inspection Handbook"
Scope and nature of the process to be followed.[2]	Compare QSIT Inspectional Objectives and "linkages" with the requirements of the QS Regulation. Determine whether the QSIT provides for the inspection of the requirements of the QS Regulation either directly through Inspectional Objectives or indirectly through "linkages". This comparison will be accomplished using CSO Chris Nelson's (FDA, CDRH GMP Expert) model "SUBSYSTEM PURPOSE, TOOLS AND RELATED SECTIONS OF THE QUALITY SYSTEM REGULATION" as the tool for comparison. CSO Nelson's model will be compared to the requirements of the QS Regulation to determine if any "gaps" exist between CSO Nelson's model and the regulation. The QSIT Inspectional Objectives and "linkages" will be compared against CSO Nelson's model to determine if any "gaps" exist between the inspectional requirements of QSIT and the regulatory requirements of the QS Regulation (via CSO Nelson's model). CSO Nelson's model was selected as an intermediary document because it has already aligned the requirements of the QS Regulation with the concept of a quality system consisting of "seven subsystems". Overall responsibility for this activity: R. Ruff (HFR-CE350)	
Acceptance criteria (if known)	QSIT Inspectional Objectives and "linkages" provide for the inspection of the requirements of the QS Regulation.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**	This activity will provide direct and objective evidence that while fulfilling the requirements necessary to meet QSIT Inspectional Objectives, the requirements of the QS Regulation are inspected. Since we are comparing the requirements of QSIT to the QS Regulation requirements, there are no apparent weaknesses in this activity.	
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.	This pre-deployment activity will demonstrate that the QSIT provides for the inspection of the requirements o the QS Regulation.	

Rev.12/18/98

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
G4	Provide broad and adequate coverage of the Quality System Regulation when conducting a comprehensive Quality System inspection.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
1	Analysis	QSIT Inspectional Objectives and narrative "linkages" described within the "QSIT Inspection Handbook"
Acceptance Criteria	QSIT Inspectional Objectives and "linkages" provide for the inspection of the requirements of the QS Regulation.	
Summary of Results	A comparison of the requirements of the Quality System Regulation (21 CFR Part 820) with CSO Chris Nelson's model "SUBSYSTEM PURPOSE, TOOLS AND RELATED SECTIONS OF THE QUALITY SYSTEM REGULATION" appears within Attachment 1. Also contained within Attachment 1 is a comparison of the QSIT Handbook Inspectional Objectives (including tasks associated with the accomplishment of these objectives as described within the narrative discussion of each objective) and linkages. Concerning CSO Nelson's model, two sections of the QS Regulation were not captured within the model ("820.1 Scope" and "820.3 Definitions"). Concerning the QSIT Handbook, twelve sections of the QS Regulation were not directly captured for review via Inspectional Objectives or narrative discussions or indirectly through linkages. The sections were: "820.1 Scope", "820.3 Definitions", "820.60 Identification", "820.65 Traceability", "820.70(f) Buildings" (all other requirements of 820.70 captured), "820.86 Acceptance Status", "820.120 Device Labeling" (requirements other than Design Control), "820.140 Handling", "820.150 Storage", "820.160 Distribution", "820.170 Installation", "820.180 Records" (other than 820.180(c)). On 3/3/99, a meeting was held between CSO Robert Ruff, NWJ-DO (sub-team leader of "QSIT Handbook Content" sub-team) and CSO Corinne Tylka, CDRH OC (acting sub-team leader in CSO Ruff's absence) to discuss and agree upon the changes required to address the deficiencies of the QSIT Handbook. The "**Comments**" column of Attachment 1 contains descriptions of the corrective actions (changes to the QSIT Handbook) necessary to address the deficiencies. CSO Tylka was assigned the responsibility for coordinating the change activities with CDRH OC support staff. CSO Tylka and/or CSO Ruff will verify that the appropriate changes have been implemented and a final QSIT Handbook will be available NLT 4/1/99. Activity references: (1) 21 CFR Part 820 (2) CSO Nelson's "SUBSYSTEM PURPOSE, TOOLS AND RELATED SECTIONS OF THE QUALITY SYSTEM REGULATION" (3) "QSIT INSPECTION HANDBOOK October 1998 Draft"	
Conclusion	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments	21 CFR Part 820, Sections "820.1 Scope" and "820.3 Definitions" are captured within an Investigator's general training. Therefore, these sections are not specifically captured within the text or linkages of the QSIT Handbook.	
Activity Champion(s)	Robert G. Ruff, CSO (HFR-CE350)	

QSIT Validation Item G4: Provide broad and adequate coverage of the Quality system Regulation when conducting a comprehensive Quality system inspection.
Key: MC = Management Controls DC = Design Controls CAPA = Corrective and Preventive Actions P&PC = Production and Process Controls SPC = Sterilization Process Controls
O1, O2...= Objective 1, Objective 2, etc. L = Linkage FC = Flow Chart Examples: 820.20(a) Quality Policy is covered by QSIT "MCO1" and "MCO2" = Management Control Objectives 1 and 2; If the requirement is covered by QSIT "P&PCO2L", it is covered by a "Linkage" from P&PC Objective 2. G4 Activity 1 Attach. 1 3 pp.

Quality System Regulation	CSO Nelson's Alignment	QSIT Coverage	Comments
820.1(a)-(e) Scope	No	No	Training issue
820.3 (a) –(aa) Definitions	No	No	Training issue
820.5 Quality System	Yes	Yes ("Getting Started")	Confirmation is an ultimate goal of QSIT
820.20 Management Respon.	Section Title	Section Title	
820.20(a) Quality Policy	Yes	Yes (MCO1, MCO2)	
820.20(b) Organization	Yes	Yes (MCO3, MCO4)	
820.20(b)(1) Resp. and Auth.	Yes	Yes (MCO3)	
820.20(b)(2) Resources	Yes	Yes (MCO3)	
820.20(b)(3) Management Rep.	Yes	Yes ("Getting Started", MCO4)	
820.20(c) Management Review	Yes (Mgt and Fac. & Equip.)	Yes (MCO1, MCO5, CAPAO10)	
820.20(d) Quality planning	Yes	Yes (MCO1)	
820.20(e) Quality system proc.s	Yes	Yes (MCO1)	
820.22 Quality Audit	Yes	Yes (MCO6)	
820.25 Personnel	Section Title	Section Title	
820.25(a) General	Yes	Yes (P&PCO6L, SPCO5L)	
820.25(b) Training	Yes (Mgt and P&PC)	Yes (P&PCO6, SPCO5)	
820.30 Design Control	Section Title	Section Title	
820.30(a) General	Yes	Yes (DCO1)	
820.30(b) Design and Dev. Plan.	Yes	Yes (DCO3)	
820.30(c) Input	Yes	Yes (DCO2, DCO4)	
820.30(d) Output	Yes	Yes (DCO2, DCO5)	
820.30(e) Review	Yes	Yes (DCO2, DCO14)	
820.30(f) Verification	Yes	Yes (DCO2, DCO6, DCO7)	
820.30(g) Validation	Yes	Yes (DCO2, DCO6, DCO8 - DCO12)	
820.30(h) Transfrer	Yes	Yes (DCO2, DCO15)	
820.30(i) Changes	Yes (Doc. & Change Control)	Yes (DCO2, DCO13)	
820.30(j) DHF	Yes (Doc. & Change Control)	Yes (DCO2)	
820.40 Document Controls	Yes	Yes (P&PCO2L, SPCO2L)	
820.40(a) Approval and Distrib.	Yes	Yes (P&PCO2L, SPCO2L)	
820.40(b) Changes	Yes	Yes (P&PCO2L, SPCO2L)	
820.50 Purchasing Controls	Yes	Yes (DCO5L, P&PCO2, SPCO2)	Add 820.50 cite to P&PC and SPC FC Box (2)
820.50(a) Evaluation of Suppliers	Yes	Yes (DCO5L, P&PCO2, SPCO2)	Covered by comment to 820.50 above
820.50(b) Purchasing data	Yes	Yes (DCO5L, P&PCO2. SPCO2)	Covered by comment to 820.50 above
820.60 Identification	Yes	No	Add as linkage to P&PCO2 & SPCO2
820.65 Traceability	Yes	No (indirectly through review of DHR)	Add as linkage to P&PCO2 & SPCO2
820.70 P&PC	Section Title	Section Title	
820.70(a) General	Yes	Yes (P&PCO2, SPCO2)	
820.70(b) Changes	Yes (Doc. & Change Control)	Yes (DCO13)	Add 820.70(b) cite to DC FC Box (13)
820.70(c) Envir. Control	Yes (Fac. & Equip.)	Yes (P&PCO2, SPCO2)	Add 820.70(c) cite to P&PC and SPC FC Box (2)
820.70(d) Personnel	Yes	Yes (P&PCO6. SPCO5)	Add 820.25 and 870.70(d) cites to P&PC FC Box (6) and SPC FC Box (5)
820.70(e) Contamination	Yes (Fac. & Equip.)	Yes (P&PCO2, SPCO2)	Add 820.70(e) cite to P&PC and SPC FC Box (2)
820.70(f) Buildings	Yes	No	Add new para. to pp. 85 & 98, just prior to "Verify that the control..." para. To state: "Verify that the building is of suitable design and contains sufficient space to perform necessary operations." Add 820.70(f) cite to P&PC and SPC FC Box (2)
820.70(g) Equipment	Yes	Yes (P&PCO2, SPCO2)	Add 820.70(g) cite to P&PC and SPC FC Box (2)
820.70(h) Manufact. Mat'l	Yes	Yes (P&PCO2, SPCO2)	Add 820.70(h) cite to P&PC and SPC FC Box (2)
820.70(i) Automated processes	Yes	Yes (P&PCO5, SPCO4)	
820.72 Insp. Meas. & Test equip.	Section Title	Section Title	

SIT Validation Item G4: Provide broad and adequate coverage of the Quality system Regulation when conducting a comprehensive Quality system inspection.

:y: MC = Management Controls DC = Design Controls CAPA = Corrective and Preventive Actions P&PC = Production and Process Controls SPC = Sterilization Process Controls
, O2...= Objective 1, Objective 2, etc. L = Linkage FC = Flow Chart Examples: 820.20(a) Quality Policy is covered by QSIT "MCO1" and "MCO2" = Management Control
)jectives 1 and 2; If the requirement is covered by QSIT "P&PCO2L", it is covered by a "Linkage" from P&PC Objective 2. G4 Activity 1 Attach. 1 3 pp.

Quality System Regulation	CSO Nelson's Alignment	QSIT Coverage	Comments
820.75 Process validation	Section Title	Section Title	
820.75(a) validation procedures	Yes	Yes (P&PCO4)	Add 820.75(a) cite to P&PC FC Box (4) and SPC FC Box (1) add statement re: procedures to SPCO1 Narrative p. 93 para. 1 "Validation studies (according to established procedures) are required...", and para. 3, sentence 2, "...must include a review of the established validation procedures and verification..."
820.75(b) monitoring and control	Yes	Yes (P&PCO2, P&PCO3, P&PCO6, SPCO2, SPCO3, SPCO5)	
820.75(c) changes, deviations	Yes	Yes (DCO13, P&PCO2, SPCO2)	Add 820.75(c) cite to P&PC FC Box (4) and SPC FC Box (1)
820.80 Acceptance Activities	Section Title	Section Title	
820.80(a) General	Yes	Yes (P&PCO2, SPCO2)	Add 820.80 cite to P&PC and SPC FC Box (2)
820.80(b) Receiving	Yes (Mat'l Control)	Yes (P&PCO2, SPCO2)	Covered by comment to 820.80(a) above
820.80(c) In-process	Yes	Yes (P&PCO2, SPCO2)	Covered by comment to 820.80(a) above
820.80(d) Final	Yes	Yes (P&PCO2, SPCO2)	Covered by comment to 820.80(a) above
820.80(e) Acc. Records	Yes	Yes (P&PCO2, SPCO2)	Covered by comment to 820.80(a) above
820.86 Acc. Status	Yes	No	Add linkage to P&PCO2 and SPCO2
820.90 Nonconforming product	Section Title	Section Title	
820.90(a) Control	Yes	Yes (P&PCO3, SPCO3)	
820.90(b) Review and Disposit.	Yes	Yes (P&PCO3, SPCO3)	
820.100 CAPA	Section Title	Section Title	
820.100(a) CAPA Procedures	Yes	Yes (DCO5L, CAPAO1 – CAPAO10)	
820.100(b) CAPA documentation	Yes	Yes (CAPAO9)	
820.120 Device Labeling	Yes	Yes (DCO5L)	p. 83 "NOTE", make the existing note "1." Add a note to state: "2. If Device Labeling is the process chosen, include in your inspection coverage of the requirements of "820.120 Device Labeling".
820.120(a) Label integrity	Yes	No	Covered by comment to 820.120 above
820.120(b) Labeling inspection	Yes	No	Covered by comment to 820.120 above
820.120(c) Labeling storage	Yes	No	Covered by comment to 820.120 above
820.120(d) Labeling operations	Yes	No	Covered by comment to 820.120 above
820.120(e) Control number	Yes	No	Covered by comment to 820.120 above
820.130 Device packaging	Yes	Yes (DCO1 – DCO15)	Add linkage to P&PCO2, SPCO2
820.140 Handling	Yes	No	Add linkage to P&PCO2, SPCO2
820.150 Storage	Section Title	Section Title	
820.150(a) Proc. control	Yes	No	Add 820.150 linkage to P&PCO2, SPCO2
820.150(b) Proc. Rec. & dispatch	Yes	No	Covered by comment to 820.150(a) above
820.160 Distribution	Section Title	Section Title	
820.160(a) Procedures	Yes	No	Add 820.160 linkage to P&PCO2, SPCO2
820.160(b) Records	Yes	No	Covered by comment to 820.160(a) above
820.170 Installation	Section Title	Section Title	
820.170(a) instruct.s & proc.s	Yes	No	Add as "linkages" following narrative of CAPAO4 "Important linkages for this activity include 820.80 Acceptance Activities, 820.90 Nonconforming Product, 820.170 Installation, 820.198 Complaint Files and 820.200 Servicing."
820.170(b) install. & records	Yes	No	Covered by comment to 820.170(a) above
820.180 Records	Yes	No	Add 820.180 linkage to P&PCO2, SPCO2
820.180(a) Confidentiality	Yes	No	Covered by comment to 820.180 above
820.180(b) Retention	Yes	No	Covered by comment to 820.180 above
820.180(c) Exceptions	Yes	Yes (MCO5, CAPAO2)	
820.181 DMR	Yes	Yes (DCO15, P&PCO2, SPCO2)	
820.181(a) Device [illegible]	Yes	Yes (DCO15, P&PCO2, SPCO2)	

)SIT Validation Item G4: Provide broad and adequate coverage of the Quality system Regulation when conducting a comprehensive Quality system inspection.

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)bjectives 1 and 2; If the requirement is covered by QSIT "P&PCO2L", it is covered by a "Linkage" from P&PC Objective 2. G4 Activity 1 Attach. 1 3 pp.

Quality System Regulation	CSO Nelson's Alignment	QSIT Coverage	Comments
820.181(c) QA procedures	Yes	Yes (DCO15, P&PCO2, SPCO2)	
820.181(d) pkg. & labeling spec.s	Yes	Yes (DCO15, P&PCO2, SPCO2)	
820.181(e) Install., Maint. Serv.	Yes	Yes (DCO15, P&PCO2L, SPCO2L)	
820.184 DHR	Yes	Yes (P&PCO2, SPCO2)	
820.184(a) dates of manuf.	Yes	Yes (P&PCO2L, SPCO2L)	
820.184(b) quantity manuf.	Yes	Yes (P&PCO2L, SPCO2L)	
820.184(c) quantity released dist.	Yes	Yes (P&PCO2L, SPCO2L)	
820.184(d) acceptance records	Yes	Yes (P&PCO2, SPCO2)	
820.184(e) prim. ID label(ing)	Yes	Yes (P&PCO2L, SPCO2L)	
820.184(f) ID, Control Num.	Yes	Yes (P&PCO2L, SPCO2L)	
820.186 QSR	Yes	Yes (P&PCO2, P&PCO6, SPCO2, SPCO5)	
820.198 Complaint Files	Section Title	Section Title	
820.198(a) Compl. Procedures	Yes	Yes (CAPAO1)	
820.198(b) Compl. Rev. & Eval.	Yes	Yes (CAPAO1)	Covered by comment to 820.170(a) above
820.198(c) Compl. Invest.	Yes	Yes (CAPAO1)	Covered by comment to 820.170(a) above
820.198(d) 803, 804 Compl.s	Yes	Yes (CAPAO1)	Covered by comment to 820.170(a) above
820.198(e) Invest. Record	Yes	Yes (CAPAO1)	Covered by comment to 820.170(a) above
820.198(f) rec. reas. access.	Yes	Yes (CAPAO1)	Covered by comment to 820.170(a) above
820.198(g) rec. access. in US	Yes	Yes (CAPAO1)	Covered by comment to 820.170(a) above
820.200 Servicing	Section Title	Section Title	
820.200(a) instruct.s and proc.s	Yes	Yes (CAPAO1)	Covered by comment to 820.170(a) above
820.200(b) Ser. Rpt. Analysis	Yes	Yes (CAPAO1)	Covered by comment to 820.170(a) above
820.200(c) 803, 804 Ser. Rpts.	Yes	Yes (CAPAO1)	Covered by comment to 820.170(a) above
820.200(d) Ser. Rpt. Document.	Yes	Yes (CAPAO1)	Covered by comment to 820.170(a) above
820.250 Statistical Techniques	Yes	Yes (CAPAO2, CAPAO3, CAPAO5, CAPAO6, P&PCO2, SPCO2)	
820.250(a) Proc.s to ID techn.s	Yes	Yes (CAPAO2, CAPAO3, CAPAO5, CAPAO6, P&PCO2, SPCO2)	
820.250(b) Proc.s for sampling	Yes	Yes (P&PCO2, SPCO2)	

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
G4	Quality System Regulation Coverage	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short Term	Analysis	Evaluate whether the instructions in the QSIT Handbook adequately address the requirements of the quality system regulation (QSR), and whether the inspection strategy assesses the quality system.
Scope and nature of the process to be followed.[2]	A group of industry representatives, regulatory consultants, and trade association executives will compare the quality system regulation with the QSIT Handbook. They will determine if the QSIT Handbook covers the key elements of the QSR. They will document their findings in a written report. The industry group consists of Don Barth, Hewlett-Packard; Rich Farb, Baxter Healthcare; Ron Johnson, Quintiles BRI; Ken Kopesky, Medtronic, Inc.; David Link, Expertech; Susan Moritz, Boston Scientific Corporation; Nancy Singer, HIMA; Robert Turocy, Picker International; and Bob Wurzel, Becton Dickinson and Company. Attachment I contains biographical information about the industry representatives. This activity is to be completed by February 25, 1999.	
Acceptance criteria (if known)	Consensus among the group members.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**		Subjective measurements by qualified experts and professionals.
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.		Two expert parties (an industry group and an FDA group) will perform this analysis independently. If the two analyses are reasonably congruent, that should provide a high degree of confidence in the findings.

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

BIOGRAPHICAL SKETCHES

Donald J. Barth is the regulatory staff manager for the Medical Products Group (MPG) of Hewlett Packard (HP). He is responsible as a senior representative and negotiator for all of HP's Washington-based medical device regulatory initiatives. He helps to influence the programs and policies that support compliance with medical device laws in all of the countries in which MPG conducts business, as well as the group-wide implementation of ISO 9000 compliance programs. Mr. Barth began his career as a design engineer specializing in electronic hardware and firmware for airborne computer systems. He joined Hewlett Packard in 1973 as a marketing support engineer. Subsequently, he held several positions in manufacturing related to systems integration and testing. He then joined the R&D group as systems integration manager of several different computer-based products, with a particular focus on tools and methodologies to ensure high quality products. He earned a master's in electrical engineering at Columbia University, and a bachelor's in electrical engineering at New York University.

Richard Farb is corporate director of regulatory compliance for Baxter International. Mr. Farb started his career with Baxter in 1965 in biomedical engineering research and development. He has experience in various positions and divisions of Baxter and has been vice president of regulatory affairs and quality assurance for two divisions. His current responsibilities include monitoring new regulatory requirements and worldwide harmonization efforts for regulatory requirements. He is the convener of ISO TC210 WG3, which has ISO jurisdiction for medical device nomenclature and symbols for use in labeling for medical devices. Mr. Farb has a bachelor's degree with concentrations in physiology and chemistry from Southern Illinois University and a master's degree from the University of Chicago.

Ronald M. Johnson is vice president for Quintiles Consulting global operations, responsible for management of the division's West Coast operations. Mr. Johnson directs and overseas the planning, development, and implementation of the Quality System Regulation including design control provisions, adverse event reporting requirements, drug and biologics GMPs, GCPs, and ISO 9000. He was with the FDA for thirty years, serving a wide array of positions in both headquarters and the field organization. During his last twelve years, he served as District Director and Regional Director in FDA's field force and as Director, Office of Compliance, Center for Devices and Radiological Health. In these positions Mr. Johnson was directly responsible for many of the agency's contemporary enforcement and compliance initiatives, particularly in the medical device area. As Director of FDA's Pacific Region, he initiated an industry outreach program to facilitate interaction and collaboration between FDA and the regulated industry.

Ken Kopesky is the director of corporate compliance and audit for Medtronic, Inc. His responsibilities are managing the overall compliance of Medtronic businesses regarding quality, regulatory, and clinical activities. He has been with Medtronic for 27 years and has held management positions in quality assurance, return product analysis, service, operations, and manufacturing development. He also is a member of GHTF Study Group 2 and serves on a number of association committees.

David M. Link has more than 35 years of experience in the medical device industry. While at Hewlett Packard Company, he served in research and development, manufacturing, and marketing functions. From 1970 to 1980, he managed the medical device program at FDA. As

the first director of the Bureau from 1974 to 1980, he was instrumental in establishing the regulatory philosophy, which permitted growth and encouraged innovation in the U.S. medical device industry. Mr. Link received his B.S. in physics from the Massachusetts Institute of Technology, his M.S. in nuclear physics from the University of Illinois, and his M.B.A. from the Harvard Graduate School of Business Administration.

Susan Moritz is the manager of corporate compliance for Boston Scientific Corporation, a multinational manufacturer and distributor of medical devices. Ms. Moritz has world-wide responsibility for the assessments of the quality systems utilized by Boston Scientific and its various divisions. Her group develops and conducts audit programs that assess the degree and extent of compliance to applicable regulations and/or practices such as the Quality System Regulation, ISO 9001, ISO 13485 and the Medical Device Directives. In this role, Ms. Moritz coordinated and conducted training for BSC personnel world wide on the design control requirements of the Quality System Regulation. Ms. Moritz has been working in the quality arena for the past 11 years and holds a bachelor's degree in biology and a master's degree in business administration.

Nancy Singer is special counsel at HIMA. In this capacity she serves as counsel for FDA enforcement matters. Previously, she was executive director of the Food and Drug Law Institute. Her food and drug career began as an attorney at the United States Department of Justice where she did litigation for the Food and Drug Administration. Subsequently she was a partner at the law firm of Kleinfeld, Kaplan and Becker. Ms. Singer received her B.S. from Cornell University, and her J.D. and LL.M. degrees from New York University Law School.

Robert L. Turocy is the corporate regulatory affairs & compliance manager for Picker International, Inc. and has more than 28 years of experience in the medical device imaging industry. During the first ten years at Picker, Mr. Turocy worked in the engineering department as a mechanical designer and a product safety specialist. The last eighteen years, he has an extensive background and experience in the regulatory requirements for medical imaging devices. Mr. Turocy is a Picker representative to NEMA Committees (Legislative & Regulatory, GMP, International, and a Chairman of the X-Ray Technical & Government Relations). He has served as a member of the FDA Technical Electronic Product Radiation Safety Standards Advisory Committee. He is a member of RAPS, AAMI, and ASQ wherein he is a Certified Quality Auditor. He is a member of IEC Working Group 15 and an alternate to other IEC Working Groups.

Robert D. Wurzel is vice president, regulatory and quality affairs at Becton Dickinson and Company in Franklin Lakes, New Jersey. Mr. Wurzel joined Becton Dickinson in 1989 and was elected a Corporate Officer in October 1994. Since 1970, Mr. Wurzel has held senior quality and regulatory affairs management positions in several international healthcare companies. Prior to his industry experience, Mr. Wurzel spent 18 years in public health and clinical laboratories. Mr. Wurzel presently is the U.S. industry representative on Working Group 4 of the Medical Device Global Harmonization Task Force. This Working Group is pursuing the harmonization of regulatory auditing worldwide. He is a member of the ANSI and AAMI Boards of Directors and was a 1997 Malcolm Baldrige National Quality Award Examiner. Mr. Wurzel holds an M.B.A. from Pepperdine University and has an undergraduate degree from Bowling Green State University (Ohio).

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
G4	Quality System Regulation Coverage	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
2	Analysis	Evaluate whether the instructions in the QSIT Handbook adequately address the requirements of the quality system regulation (QSR) and whether the inspection strategy adequately assesses the quality system
Acceptance Criteria	There was consensus among the group members: Don Barth, Hewlett-Packard; Rich Farb, Baxter Healthcare; Ron Johnson, Quintiles BRI; Ken Kopesky, Medtronic, Inc.; David Link, Expertech; Susan Moritz, Boston Scientific Corporation; Nancy Singer, HIMA; Robert Turocy, Picker International; and Bob Wurzel, Becton Dickinson and Company.	
Summary of Results	The instructions in the QSIT Handbook expressly cover the four major subsystems of the QSR and can be linked to the remaining provisions in the QSR as indicated in the attached chart. Each firm's method of applying the various provisions of the QSR will depend on its products and operations. Ultimately, the depth (sampling tables) and breadth (linkages) of the inspection will depend on the risk of the device, and the firm's compliance with the requirements.	
Conclusion	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments		
Activity Champion(s)	Nancy Singer, Special Counsel, HIMA Ken Kopesky, Director of Corporate Compliance and Audit, Medtronic, Inc.	

Rev. 2/12/99

Chart Indicating Linkages Between QSIT and the Quality System Regulation

The left column is a breakdown of the QSIT coverage in outline form. The right column is a listing of the sections of 21CFR 820. The right column also identifies the link(s) to the QSIT Outline.

QSIT Outline[1]

A Management Controls:

1. Quality policy
2. Management review
3. Quality audit
4. Quality plan
5. Quality system procedures
6. Organizational structure, responsibility, authority and necessary resources
7. Management representative
8. Suitability and effectiveness of the quality system is reviewed

B Design Controls:

1. Design control procedures
2. Design plan – assigned responsibilities, interfaces and risk analysis
3. Design inputs
4. Design outputs essential for proper functioning
5. Acceptance criteria
6. Design verification
7. Design validation - user needs and intended uses
8. Design validation – no unresolved discrepancies
9. Software validation
10. Performance of risk analysis
11. Validation with production samples
12. Design change control
13. Design reviews
14. Design Transfer

C Corrective and Preventive Action

1. Identify appropriate sources of information
2. Information is analyzed
3. Information is complete, accurate and timely
4. Statistical methods and completeness
5. Failure analysis commensurate with the risks
6. Root cause analysis
7. Appropriate actions taken and documented
8. Information disseminated – management review

D Production and Process Controls

1. Product and Process Control Procedures
2. Controls and monitors
3. Device History Records
4. Nonconformity actions
5. Equipment adjustment, calibration and maintenance
6. Validation study
7. Software validation
8. Personnel qualifications

21 CFR Section 820 Plus Linkages to the QSIT Outline on the Left

820.1 Scope - none
820.3 Definitions – none
820.5 Quality system – A1-A8
820.20 Management responsibility – A1-A8
820.22 Quality audit – A3
820.25 Personnel – A6, D8
820.30 Design controls – B1-B14
820.40 Document controls – A5, A8, B1, B2, B12, B13, B14, C3, C7, C8, D1, D3, D6-D8
820.50 Purchasing controls – B5, B6, B12, C6, C7, D2
820.60 Identification – A5, B14, D1, D2
820.65 Traceability – A5, B14, D1, D2
820.70 Production and process controls – A4, A5, C2 – C7, D1 – D8
820.72 Inspection, measuring, and test equipment – A5, C2 – C7, D1 - D8
820.75 Process validation – B6 – B8, D5 – D7
820.80 Receiving, in-process, and finished device acceptance – A4, A5, C1 – C8, D1 – D5
820.86 Acceptance status – A4, D1, D2
820.90 Nonconforming product – A2, A4, A5, C1 – C8
820.100 Corrective and preventive action – C1 – C8
820.120 Device labeling – A5, B3, B7, D1, D2
820.130 Device packaging – B3, B7, D1, D2
820.140 Handling – A5, D1, D2
820.150 Storage – A5, D1, D2
820.160 Distribution – A5, D1, D2
820.170 Installation – A5, B3, B4, B7, D1, D2
820.180 Records, General requirements – A4, A5, B2
820.181 Device master record – A4, A5, B4, B5, B14, D1, D2
820.184 Device history record – A4, A5, D3
820.186 Quality system record – A4, A5, B12, B14, D1 – D8
820.198 Complaint files – A5, C1 – C8, D4
820.200 Servicing – A4, A5, B7, D1, D2
820.250 Statistical techniques – A4, A5, B2, B5, B6, B7, B10, B11, C4, D6

[1] The QSIT Outline numbering does not relate to the numbering in the QSIT Handbook.

O1A

Increase Consistency Among Districts

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
O1A (Activity 1)	Increase consistency among districts for conducting comprehensive Quality System inspections of medical device manufacturers.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Analysis	Inspectional Objectives and narrative "linkages" described within the "QSIT Inspection handbook"
Scope and nature of the process to be followed.[2]	Compare the structure of a QSIT inspection described within the QSIT Inspection Handbook to that of the current comprehensive inspection technique described within DRAFT CP 7382.830 INSPECTION OF MEDICAL DEVICE MANUFACTURERS (May 1997) and the GUIDE TO INSPECTIONS OF MEDICAL DEVICE MANUFACTURERS (December 1997). Determine whether QSIT or the existing technique provides for a more defined, succinct and prescriptive methodology for the comprehensive inspection of medical device manufacturers. Providing a well defined, succinct and prescriptive methodology to all FDA districts will help ensure increased consistency in the inspection of medical device manufacturers among thos districts. Overall responsibility for this activity: R. Ruff (HFR-CE350)	
Acceptance criteria (if known)	QSIT inspectional objectives and linkages provide for a more well defined, succinct and prescriptive methodology for the inspection of medical device manufacturers than the current technique.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**	This activity will provide direct and objective evidence that the QSIT provides a more well defined, succinct and prescriptive methodology for the inspection of medical device manufacturers than the current technique. A potential weakness in this activity is that some may debate whether a prescriptive technique is as effective as a less prescriptive technique.	
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.	This pre-deployment activity will demonstrate that the QSIT technique is more well defined, succinct and prescriptive than the current technique via a direct comparison.	

Rev.12/18/98

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
O1A	Increase consistency among districts for conducting comprehensive Quality System inspections of medical device manufacturers.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
1	Analysis	Inspectional Objectives and narrative "linkages" described within the "QSIT Inspection Handbook"
Acceptance Criteria	QSIT inspectional objectives and linkages provide for a more well defined, succinct and prescriptive methodology for the inspection of medical device manufacturers than the current technique.	
Summary of Results	A comparison of the structure of a "QSIT" inspection described within the QSIT Inspection Handbook to that of the current comprehensive inspection technique ("T1997C") described within DRAFT CP 7382.830 INSPECTION OF MEDICAL DEVICE MANUFACTURERS (May 1997) and the GUIDE TO INSPECTIONS OF MEDICAL DEVICE MANUFACTURERS (December 1997) was conducted and analyzed. A table documenting the comparison appears as Attachment 1. Both techniques were described in terms of "Tasks". Each task was extracted from the appropriate inspectional reference and documented on Attachment 1. This activity attempted to extract only the tasks which an inspector is instructed to complete during a QSIT or T1997C inspection. Where either technique consisted of narrative discussions of regulatory requirements, no tasks were inferred. An analysis of the number of tasks required to accomplish (1) a comprehensive inspection of a non-sterile medical device manufacturer and (2) a comprehensive inspection of a sterile medical device manufacturer was conducted. This analysis appears as Attachment 2. For this activity the following assumptions were made (1) QS Regulation, MDR, Tracking and Corrections and Removals requirements were all applicable and (2) the manufacturer determined bioburden and used a contract irradiation sterilization service. In addition, Attachment 2 includes an analysis of the number of "References Providing Inspectional Instructions" that are required to be maintained and utilized during QSIT and T1997C inspections. Results include: 1. The comprehensive inspection of a non-sterile medical device manufacturer using QSIT requires 139 tasks and 1 reference. The comprehensive inspection of a non-sterile medical device manufacturer using T1997C requires 188 tasks and 3 references. 2. The comprehensive inspection of a sterile medical device manufacturer using QSIT requires 151 tasks and 1 reference. The comprehensive inspection of a sterile medical device manufacturer using T1997C requires 231 tasks and 4 references. 3. T1997C does not reflect contemporary inspectional requirements. E.g. (1) T1997C instructs the investigator to use the "Design Control Inspectional Strategy included in CP7382.830 Attachment F"and provides guidance from the "Transition" period. The referenced strategy has been obsolete and the transition period has been over since June of 1998. 4. QSIT provides a sampling methodology or a specific number when records are reviewed. T1997C provides sampling instructions only in CP7382.830A for field examination of sterile packages. In a number of tasks, T1997C requires inspection of "all" records. E.g. (1) "Review all records for the proper disposition of nonconforming products for assurance that use of nonconforming product has not resulted in the distribution of defective devices.", and (2) "Verify history records representing individual devices or lots of devices exist for all finished devices manufactured." This activity has demonstrated that QSIT will accomplish a comprehensive inspection (including Corrections and Removals) of a non-sterile medical device manufacturer in approximately 26% fewer tasks than T1997C (excluding Corrections and Removals) and utilizing approximately 67% fewer reference sources. This activity has demonstrated that QSIT will accomplish a comprehensive inspection (including Corrections and Removals) of a sterile medical device manufacturer in approximately 35% fewer tasks than T1997C (excluding Corrections and Removals) and utilizing 75% fewer reference sources. Through the use of sampling, QSIT provides "end points" for the review of records that are not prescribed in T1997C. Based upon the following facts (1) there are less tasks associated with QSIT (2) there is only one reference source associated with QSIT (also consider ease of maintenance) (3) the number of records reviewed is prescribed in QSIT and (4) QSIT contains contemporary inspectional requirements, QSIT has been demonstrated to provide a more well defined, succinct and prescriptive methodology for the comprehensive inspection of medical device manufacturers than T1997C.	
Conclusion	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments	This analysis was conducted prior to the conclusion of QSIT Field Test activities. The number of tasks required to conduct a QSIT inspection may change (increase or decrease) based upon the QSIT Field Test activities.	
Activity Champion(s)	Robert G. Ruff, CSO (HFR-CE350)	

QSIT Validation Worksheet Item O1A Activity 1 Comparison (Attachment 1, 10 pages)

QSIT		T1997C
1. Preannouncement Activities	Reference: QSIT Handbook	III A. 1. "When conducting all routine GMP inspections you are required to start the inspection with a review of: (1) complaints
Task 1 - Request and review copies of Quality Policy and High Level Quality System Procedures (Management Review Procedure, Quality Plan)		Task 1 - Determine if the firm has received complaints Task 2 - Review a sample of complaints (start from most current and work backwards to 24 months max., total depends on a number of factors e.g. skill of Invet. and storage medium) Task 3 - Ascertain what files contain complaints
2. Interview Management Representative	Reference: QSIT Handbook	
Task 1 - Management Representative (or designee) interviewed prior to the inspection of each subsystem (min. 4 ea. interviews)		Task 4 - Trend complaints (if not done by firm) Task 5 - Analyze to ID existing or potential causes of nonconforming product or quality problems Task 6 - Determine if adequate complaint investigation is performed Task 7 - Determine identity of individuals reviewing complaints Task 8 - Determine the qualifications of the individuals reviewing complaints Task 9 - Confirm all complaints are covered and reported Task 10 - If no complaints received, determine if provisions are in place Task 11 - If no complaints received, determine who will be responsible
3. Inspect Management Controls	Reference: QSIT Handbook	
Objective 1: Verify... Task 1 - Quality Policy Task 2 - Management Review Procedures Task 3 - Quality Audit Procedures Task 4 - Quality System Procedures and Instructions ...have been defined and documented. Objective 2: Verify... Task 1 - Quality Policy has been implemented Objective 3: Review established organizational structure to assure it includes provisions for... Task 1 - responsibilities Task 2 - authorities Task 3 - resources Objective 4: Confirm... Task 1 - Management Representative has been appointed Evaluate... Task 2 - Purview of the Management Representative Objective 5: Verify... Task 1 - Management Reviews are being conducted		and MDR reports (see Attachment A, Section I (B)..." Note: "Attachment A" is a list of "Class I Devices exempt from most of the GMP Requirements By Classification Regulations" Attachment C contains guidance for determining manufacturer compliance with the MDR regulation. Task 1 - Determine if there are written MDR procedures Task 2 - Determine if they are complete Task 3 - Determine if they are followed Task 4 - Determine if event files are maintained Task 5 - Determine if the file is easy to ID/access Task 6 - Determine if files contain the necessary reports and correspondence Task 7 - Determine if the files contain documentation regarding decisions not to file an MDR Task 8 - Document credentials of qualified medical staff making decision not to file Task 9 -Determine if the file contains copies of failure analyses, etc. Task 10 - Determine if MDR files contained in GMP files are readily IDable

Objective 6: Verify...
Task 1 - Quality Audits are conducted at sufficient frequency
Task 2 - Effectiveness of Audit
Task 3 - Independence of Auditor
Task 4 - Adequacy of Audit Procedure
Task 5 - Communication of findings to Upper Management
Task 6 - Corrective Actions implemented and Re-audits

4. Inspect Design Controls

Reference: QSIT Handbook

Objective 1: Select Design Project (if applicable)
Task 1 - Select a design project that meets 820.30(a)

Objective 2: Verify...
Task 1 - Design Control Procedures are defined and documented
Task 2 - DC Procedures address the specific requirements of 820.30

Objective 3: Review...
Task 1 - The Design and Development Plan

Objective 4: Confirm...
Task 1 - Design Inputs were established
Review...
Task 2 - Sources of input
Determine...
Task 3 - That relevant aspects were included

Objective 5: Verify...
Task 1 - Essential outputs are identified
Review...
Task 2 - Method for identifying essential outputs

Objective 6: Confirm...
Task 1 - Verification acceptance criteria established prior to activity
Task 2 - Validation acceptance criteria established prior to activity

Objective 7: Determine if...
Task 1 - Verification confirms output meets input (Sample Tables)

Objective 8: Confirm...
Task 1 - Validation data shows user needs and intended uses met

Task 11 - Examine files for computer generated "deficiency" letters
Task 12 - If deficiency letter received discuss and determine if problem resolved

III A. 1. (cont'd) "...(2) changes which the manufacturer has made in the design or manufacturing process,

Task 1 - Review design changes (see below "Design Control Report and Guidance")
Task 2 - Review manufacturing process changes
Task 3 - Determine if changes are validated and/or verified
Task 4 - Determine if there are a series of changes for the same problem
Task 5 - Document all design changes on DCIS Report

and (3) records of production lots which failed in-process or finished device testing.

Task 1 - Determine if the firm released lots that failed to meet specifications
Task 2 - Review DHR's or in-process control records of lots that have been rejected
Task 3 - Report and document shipment
Task 4 - Evaluate MRB rationales (if applicable)
Task 5 - Review re-work records
Task 6 - Determine if rework is adequate
Task 7 - Determine that rework does not affect S & E
Task 8 - Determine if sampling plans for inspection are acceptable
Task 9 - Determine if sampling plans for rework are acceptable
Task 10 - Analyze and trend nonconforming product records
Task 11 - Inspect data for repeat component failures
Task 12 - Determine if procedures to control nonconforming product are established
Task 13 - Determine if procedure is complete
Task 14 - Review all records of nonconforming product to ensure they didn't ship defective product.
Task 15 - Review concessions
Task 16 - Evaluate concessions for 510(k) applicability

"Any indications of problems that your review identifies will provide a focus for your inspection. If you do not find indications of problems after reviewing the above records, complete the inspection as directed in the Guide to Inspection of Medical Device Manufacturers and the Design Control Inspectional Strategy..."

Select devices for coverage based on above findings (plus service record review) or "....because of what they are made of or how they are made, have the highest potential for problems that could result in the design, manufacture and/or distribution of unsafe or unreliable devices."

Objective 9: Confirm...
Task 1 - Validation did not leave unresolved discrepancies

Objective 10: Confirm...
Task 1 - Software is validated (if device contains software)

Objective 11: Confirm...
Task 1 - Risk Analysis was completed

Objective 12: Determine if...
Task 1 - Validation was accomplished using initial production devices or their equivalents
Review...
Task 2 - Equivalency when equivalent devices are used

Objective 13: Confirm...
Task 1 - A pre-production change was controlled appropriately
Task 2 - A post-production change was controlled appropriately

Objective 14: Determine...
Task 1 - If design reviews were conducted
Confirm...
Task 2 - An individual without direct responsibility was included
Task 3 - Outstanding action items have or are being resolved

Objective 15: Determine if...
Task 1 - The design was correctly transferred
Compare...
Task 2 – The device master record against outputs (Sample Tables)

Servicing:

Task 1 - Determine if adequate system is in place to screen service and repair reports for complaints
Task 2 - Cross- reference service related complaints in complaint handling system
Task 3 - Review service reports for MDR events

Corrective and Preventive Actions:

Task 1 - Determine whether the firm has conducted any recalls or market withdrawals

III A. 6 "Confirm that all subject recalls conducted by the establishment since the last inspection have, in fact, been reported to the district office. Also review files to determine if all events filed by the establishment as Class III recalls have been properly classified..."

Task 2 - Determine if the firm has established CAPA procedures
Task 3 - Determine if the firm analyzes repair and service records for warranty failure trends
Task 4 - Review records of investigations to ID common failure trends
Task 5 - Compare these trends with corrective action documentation
Task 6 - Conduct "detailed" inspection of CAPA records
Task 7 - Review trending information performed by firm
Task 8 - Review corrective actions already implemented
Task 9 - Review service records (amount relates to same criteria as for complaints)
Task 10 - Determine if service reports were analyzed for existing or potential causes of nonconforming product or other quality problems
Task 11 - Review for trends by sorting "fields"

Process Validation:

Task 1 - Determine if the results of the process cannot be fully verified by subsequent inspection and test
Task 2 - Determine if processes are contributing to defective products
Task 3 - Review process validation to ID defect characteristics and expected rates
Task 4 - Review first and last article test results
Task 5 - If problems, question control parameters, environmental conditions, components etc.
Task 6 - Determine whether adequate prospective or retrospective validation was performed

5. Inspect CAPA	Reference: QSIT Handbook

Objective 1: Verify...
Task 1 - CAPA Procedures are defined and documented
Task 2 - CAPA Procedures address the specific requirements of 820.100

Objective 2: Determine if...(re: corrective action) .
Task 1 - Appropriate sources of quality data have been identified
Confirm...
Task 2 - The data is being analyzed

Objective 3: Determine if...(re: preventive action)
Task 1 - Appropriate sources of quality data have been identified
Confirm...
Task 2 - The data is being analyzed

Objective 4: Verify that quality data is... (Sample Tables)
Task 1 - Entered
Task 2 - Complete
Task 3 - Accurate
Task 4 - Timely

Objective 5: Verify...
Task 1 - Appropriate statistical methods are employed
Task 2 - Non-statistical methods are employed
Determine if...
Task 3 - Results are compared across different data sources
Objective 6: Determine if... (Sample Tables)
Task 1 - Failure investigation procedures are followed
Task 2 - Investigation is commensurate with the significance and risk
Task 3 - Root cause identified
Verify...
Task 4 - Control for prevention of distribution of nonconforming product

Objective 7: Determine if... (Sample Tables)
Task 1 - Appropriate actions are taken

Objective 8: Determine if...
Task 1 - The action(s) were effective
Task 2 - The action(s) were verified or validated
Confirm...
Task 3 -The action(s) do not adversely affect the finished device

Components:

Task 1 - Determine if nonconforming devices are manufactured because of nonconforming components (review complaints, concessions, etc.)
Task 2 - Determine if appropriate statistical method is used for acceptance sampling
Task 3 - Review and evaluate test and/or screening of components
Task 4 - For JIT vendors, review audit procedure and schedule

Quality Audits:

Task 1 - Determine if written audit procedure exists
Task 2 - Determine frequency of audits
Task 3 - Interview an auditor (if possible)
Task 4 - Determine whether corrective action by upper management is being taken
Task 5 - Confirm re-audits of deficient matters are conducted when required

Design Controls:

Note: Although the DRAFT CP 7382830 and December 1997 Guide to Inspection of Medical Device Manufacturers refer to the Design Control Inspectional Strategy, for this comparison, I used the tasks described in the Design Control Report and Guidance which is contemporary.

Task 1 - Select a device subject to design controls
Task 2 - Determine whether the design project related to an original design or modification to an existing design
Task 3 - Determine at what stage in the design project, design controls were applied
Task 4 - Determine if Design and Development plan is complete
Task 5 - Determine whether the plan was reviewed, updated and approved
Task 6 - Review design input procedures
Task 7 - Confirm design input procedures are complete
Task 8 - Review process for resolving incomplete, ambiguous...requirements
Task 9 - Review how design input addresses user interface
Task 10 - Confirm design input is reviewed, approved and documented
Task 11 - Review design output procedures
Task 12 - Confirm design outputs expressed in terms that allow comparison to inputs
Task 13 - Review technique for identification of essential outputs
Task 14 - Confirm that design output is reviewed, approved and documented
Task 15 - Review design review procedures
Task 16 - Assure the procedures ensure reviews are comprehensive
Task 17 - Confirm manufacturer has IDed appropriate stages for review
Task 18 - Review documentation from at least one design review

Objective 9: Verify that... (Sampling Tables)
Task 1 - Corrective and preventive actions are documented
Task 2 - Corrective and preventive actions have been implemented

Objective 10: Determine if...
Task 1 - Information is properly disseminated to responsible individuals
Task 2 - Information is disseminated for management review

6. Inspect P&PC

Reference: QSIT Handbook

Objective 1: Select a process...
Task 1 - Select a process based on criteria

Objective 2: Review... (Sample Tables)
Task 1 - The procedures for the process selected
Task 2 - The control methods
Task 3 - The monitoring methods

Confirm...
Task 4 - Equipment is maintained
Task 5 - Test equipment is controlled
Task 6 - Test equipment is calibrated

Verify...
Task 7 - DHR's vs. DMR
Task 8 - Purchasing controls are employed
Task 9 - Receiving acceptance activities
Task 10 - In-process acceptance activities
Task 11 - Finished device acceptance activities
Task 12 - Environmental controls
Task 13 - Contamination controls
Task 14 - Statistical techniques

Objective 3: If problem with DHR's...

Determine if...
Task 1 - Nonconformance(s) were recognized
Task 2 - Nonconformance(s) handled appropriately
Task 3 - Quality data fed to CAPA

Review...
Task 4 - Equipment adjustment
Task 5 - Equipment calibration
Task 6 - Equipment maintenance
Task 19 - Confirm problems or action items were addressed
Task 20 - Review design verification procedures
Task 21 - Review verification methods and data
Task 22 - Review procedures for design validation
Task 23 - Confirm validation was accomplished per procedure
Task 24 - If "equivalent" devices used, review how "equivalency" was determined
Task 25 - Review clinical and non-clinical evaluations
Task 26 - Review software validation (where applicable)
Task 27 - Identify risk analysis tools and techniques
Task 28 - Confirm data demonstrates needs of user and intended use met
Task 29 - Review design transfer procedure
Task 30 - Confirm that design transfer procedures were followed
Task 31 - Compare significant elements of DMR to finished design outputs
Task 32 - Review design change procedures
Task 33 - Confirm changes were made according to procedure
Task 34 - Confirm procedure assures changes are validated or verified
Task 35 - Confirm there is written justification when verified but not validated
Task 36 - Confirm design changes are reviewed, approved and documented
Task 37 - Confirm changes were appropriately communicated
Task 38 - Confirm DHF contains necessary elements
Task 39 - Confirm the firm can identify each device in design family or group

PMA Devices

Task 1 - Determine if site is approved

Medical Device Tracking

Task 1 - Determine if device is a tracked device
Task 2 - Determine whether procedures exist
Task 3 – Determine adequacy of procedures

Follow-up to OAI Inspection: (if applicable)

Task 1 - Determine whether all previous FDA-483 observations were investigated
Task 2 - Determine implementation of all corrective actions re: previous FDA-483

Personnel:

Task 1 - Look for examples of potential training deficiencies
Task 2 - Verify firm has procedures for identifying training needs

Evaluate validation study...
Task 7 - Instruments calibrated
Task 8 - Instruments maintained
Task 9 - Confirm predetermined product specifications
Task 10 - Test sampling plans valid
Task 11 - Objective evidence spec.s met consistently
Task 12 - Tolerances challenged
Task 13 - Equipment properly installed
Task 14 - Equipment properly adjusted
Task 15 - Equipment properly maintained
Task 16 - Monitoring instruments calibrated
Task 17 - Monitoring instruments maintained
Task 18 - Changes properly challenged
Task 19 - Operators appropriately qualified

Objective 5: Confirm software is validated...
Review...
Task 1 - Software requirements document
Task 2 - Software validation protocol
Task 3 - Software validation activities
Task 4 - Software change controls
Task 5 - Software validation results

Objective 6: Verify... (Sample Tables)
Task 1 - Employees are aware of device defects
Task 2 - Employees conducting QC inspections aware of defects and errors
Task 3 - Review training records
Task 4 - Verify all personnel have been made aware of defects
Task 5 - Verify personnel involved with verification or validation are aware of defects, etc.

Document Controls:

Task 1 - Verify written procedures are signed and dated as approved
Task 2 - Verify DMR is signed and dated as approved
Task 3 - Verify DHR is signed and dated as approved
Task 4 - Assure all documents are available at point of use
Task 5 - Review document change records

Purchasing Controls:

Task 1 - Verify written procedures capture necessary requirements
Task 2 - Verify firm's evaluation of suppliers
Task 3 - Verify type and extent of control activities is defined based on evaluations
Task 4 - Verify that there are records of acceptable suppliers
Task 5 - Verify the firm has written requirements for purchased items and services

Identification and Traceability:

Task 1 - Compare DHR's with DMR to ensure appropriate components were used in each stage of manufacturing
Task 2 - Compare DHR's against incoming and in-process acceptance activities to ensure only "passed" product was used

Production and Process Controls:

Task 1 - Verify specifications and documented work instructions are provided for all processes in which variations could result in failure of the finished device to meet specifications
Task 2 - Verify specification and procedure changes are reviewed and approved using a formal process and procedure
Task 3 - Verify new specifications and procedures are reviewed and approved using a formal process and procedure
Task 4 - Determine if components or devices are reworked
Task 5 - Verify written rework procedures are provided
Task 6 - Determine if manufacturer has assessed effect of rework
Task 7 - Determine if this assessment is documented

7. Inspect Sterilization Process Controls **Replaces P&PC if Sterilization is process selected for inspection**	Reference: QSIT Handbook

Objective 1: Review...
Task 1 - Validation Study Summary and Approval
Or, assess complete validation study ...
Task 1 - Instruments calibrated
Task 2 - Instruments maintained
Task 3 - Confirm predetermined product specifications
Task 4 - Confirm predetermined package specifications
Task 5 - Test sampling plans valid
Task 6 - Objective evidence spec.s met consistently
Task 7 - Tolerances challenged
Task 8 - Equipment properly installed
Task 9 - Equipment properly adjusted
Task 10 - Equipment properly maintained
Task 11 - Monitoring instruments calibrated
Task 12 - Monitoring instruments maintained
Task 13 - Changes properly challenged
Task 14 - Operators appropriately qualified
Task 15 - Periodic assessments of process adequacy

Objective 2: Review...
Task 1 - The procedures for the sterilization process selected
Task 2 - The control methods
Task 3 - The monitoring methods
Confirm...
Task 4 - Equipment is maintained
Task 5 - Test equipment is controlled
Task 6 - Test equipment is calibrated
Verify...
Task 7 - DHR's vs. DMR
Task 8 - Purchasing controls are employed
Task 9 - Receiving acceptance activities
Task 10 - In-process acceptance activities
Task 11 - Finished device acceptance activities
Task 12 - Packaging integrity acceptance activities
Task 13 - Environmental controls
Task 14 - Contamination controls
Task 15 - Statistical techniques

Task 8 - Verify that there are documented inspections of environmental controls
Task 9 - Verify the washing and toilet facilities are clean and adequate
Task 10 - Verify clothing requirements and controls are adequate
Task 11 - Verify that contamination procedures exist
Task 12 - Verify that the contamination procedures are adhered to
Task 13 - Verify eating, drinking and smoking is limited to designated areas (if applicable)
Task 14 - Verify that sewage, trash etc. is handled appropriately
Task 15 - Verify personnel are clean, healthy, etc.
Task 16 - Verify personnel are excluded from affected operations when appropriate
Task 17 - Verify written procedures require employs to report health conditions
Task 18 - Verify there are written maintenance procedures and schedules
Task 19 - Verify there is written documentation of maintenance activities
Task 20 - Verify equipment inherent limitations are visibly posted
Task 21 - Verify periodic inspections are conducted of maintenance schedules
Task 22 - Verify that these inspections are per a written procedure
Task 23 - Verify manufacturing material is removed or limited
Task 24 - Verify there are written procedures for the control of man. material
Task 25 - Verify software of production equipment is validated
Task 26 - Verify software of quality system equipment is validated
Task 27 - Verify changes to software are validated and approved
Task 28 - Verify validation activities are documented
Task 29 - Verify inspection, measuring and test equipment is checked
Task 30 - Verify inspection, measuring and test equipment is calibrated
Task 31 - Verify inspection, measuring and test equipment is inspected
Task 32 - Verify inspection, measuring and test equipment is maintained
Task 33 - Verify these activities are according to written procedures
Task 34 - Verify these activities are documented
Task 35 - Verify the procedures include provisions for handling, preservation and storage
Task 36 - Verify Handling, preservation, etc. activities are documented
Task 37 - Verify written calibration procedures include specific limits, etc.
Task 38 - Review calibration records
Task 39 - Verify remedial actions are documented when limits are exceeded
Task 40 - Verify standards are traceable to nat'l or int'l standard
Task 41 - Verify calibration records are displayed on or near ea. piece of equipment
Task 42 - Verify calibration records include equip. ID, calib. dates, next calib. date

Objective 3: If problem with DHR's... Determine if...
Task 1 - Nonconformance(s) were recognized
Task 2 - Nonconformance(s) handled appropriately
Task 3 - Quality data fed to CAPA
Task 4 - Re-test is appropriate (if applicable)
Task 5 - Effects of re-sterilization are understood (if applicable)
Review...
Task 6 - Equipment adjustment
Task 7 - Equipment calibration
Task 8 - Equipment maintenance

Objective 4: Confirm software is validated...
Review...
Task 1 - Software requirements document
Task 2 - Software validation protocol
Task 3 - Software validation activities
Task 4 - Software change controls
Task 5 - Software validation results

Objective 5: Verify... (Sample Tables)
Task 1 - Employees are aware of device defects
Task 2 - Employees conducting QC inspections aware of defects and errors

Sterilization EIR Reporting Requirements:

Item 1 - ID all sterilization processes used by the firm
Item 2 - ID sterilization process covered
Item 3 - ID of standard used for process covered
Item 4 - Location of sterilization sites
Item 5 - Division of responsibilities for sterilization activities
Item 6 - SAL
Item 7 - Whether or not parametric release is used

Labeling and Packaging control:

Task 1 - Verify the firm has labeling operation control procedures
Task 2 - Verify the procedures are adequate
Task 3 - Verify packaging and shipping containers are adequate

Handling, Storage, Distribution and Installation

Task 1 - Review distribution records against final inspection and quarantine records
Task 2 - Review records of receipt and dispatch to confirm procedures are followed
Task 3 - Review service records to ensure service is not required immediately after installation

Records:

Task 1 - Encourage firm to mark records they deem to be confidential
Task 2 - Review DMR for completeness
Task 3 - Ensure there is a formal method for approving and changing the DMR
Task 4 - Verify there are DHR's for all finished devices
Task 5 - Verify DHR's contain evidence that labeling was examined prior to use

Pre-Approval Device Inspection (PMA, and Class III 510(k):

Task 1 - Verify accuracy of information submitted
Task 2 - Assess the firm's ability to meet the QS Reg.
Task 3 - Determine if changes were communicated to review staff

Sterile Devices:

Task 1 - Obtain records to document any deficiencies related to validation
Task 2 - Determine if firm is or may be manufacturing nonsterile devices (via review of release records, process records, bioburden records, product and packaging changes, etc.)
Task 3 - Review records of lots with positive sterility test results
Task 4 - Review records of lots with positive BI results
Task 5 - Review any re-sterilization records due to process failures
Task 6 - Verify re-sterilized lots were adequately reworked
Task 7 - Verify re-sterilized lots were adequately tested

CP 7382.830A contains a number of additional tasks to be accomplished for a sterile device. E.g. Attach. B requires approximately thirty-six additional tasks for the inspection of a manufacturer who uses an irradiation contract sterilizer

Inspect MDR, C&R and Tracking (Conducted during inspection of CAPA)	Reference: QSIT Handbook

MDR:

Objective 1: Verify...
Task 1 - Written MDR procedures address the requirements of 803.17

Objective 2: Verify... (Sample Tables)
Task 1 - MDR event files are prominently IDed
Task 2 - MDR event files are easy to access
Confirm...
Task 3 - MDR event files contain the necessary information

Objective 3: Confirm... (Sample Tables)
Task 1 - That the appropriate MDR information is identified
Task 2 - That the appropriate MDR information is reviewed
Task 3 - That the appropriate MDR information is documented
Task 4 - That the appropriate MDR information is filed

Objective 4: Confirm... (Sample Tables)
Task 1 - That the procedures are effective (review unreported event files)
Determine...
Task 2 - The firm's rationale for not filing MDR's for apparent MDR events

C&R:

Objective 1: Determine...
Task 1 - Whether the firm has implemented any corrections
Task 2 - Whether the firm has implemented any removals

Objective 2: Confirm... (Sample Tables)
Task 1 - Select and review files of reported C&R's
Task 2 - Select and review files of other CAPA's for C&R's

Objective 2: Verify... (Sample Tables)
Task 1 - Files of non-reportable C&R's are maintained
Task 2 - Files contain the necessary information
Task 3 - The files are retained for the appropriate amount of time

Confirm...
Task 4 - The files do not contain evidence of unreported recalls
Task 5 - Any claims for exemption
Verify...
Task 6 - If device was sold to another firm, files were transferred

Tracking:

Objective 1: Determine...
Task 1 - If the firm manufactures a tracked device
Task 2 - If yes, if the firm is aware of its tracking obligations
Confirm...
Task 3 - If the device was purchased form another firm, that the prior firm's tracking records (or equivalents) were obtained

Objective 2: Verify...
Task 1 - The firm has established a written tracking procedure
Task 2 - The procedure contains the necessary requirements
Task 3 - Information requested by FDA is provided as requested
Task 4 - Information requested by FDA is provided within timeframes

Objective 3: Confirm...
Task 1 - The firm has audited its tracking system
Task 2 - The audit procedures are complete

OIA Activity 1 Attachment 2 (1 page)

Number of Tasks and Number of References Required to Conduct (1) A Comprehensive Inspection of a Non-Sterile Medical Device Manufacturer and (2) A Comprehensive Inspection of a Sterile Medical Device Manufacturer

	Number of Tasks Required to Provide Inspectional Coverage		Number of References Providing Inspectional Instructions		
Regulatory Requirement	**QSIT**	**T1997C**	**QSIT**	**T1997C**	**Comments**
Quality System Regulation (non-sterile device)	110	171*	1	3**	*Does NOT include: confirmation of PMA site approval or PMA, Class III 510(k) tasks (4 ea.) **(1) DRAFT CP 7382.830, (2) Guide to Inspections of Medical Device Manufacturers (3) Design Control Report and Guidance
Quality System Regulation (sterile device***)	122	214*	1	4****	***Device man. determines bioburden, contract irradiation sterilization ****(1) DRAFT CP 7382.830 (2) Guide to Inspections of Medical Device Manufacturers (3) Design Control Report and Guidance (4) CP 7382.830A
Medical Device Reporting	10	12	1	2	
Medical Device Tracking	9	3	1	2	
Medical Device Corrections and Removals	10	2	1	0	
Total Number of Tasks (non-sterile device)	**139**	**188**			
Total number of references required			1	3**	
Total Number of tasks (sterile device*)**	**151**	**231**			
Total number of references required			1	4****	

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
O1A (Activity 2)	Increase consistency among districts for conducting comprehensive Quality System inspections of medical device manufacturers.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	The comparison of FDA 483 items to the steps in the flowcharts in the QSIT Handbook.
Scope and nature of the process to be followed.[2]	During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct comprehensive medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections. Beginning the week of 1/11/99, the FDA 483s for the QSIT Study inspections will be reviewed by C. Tylka, HFZ-320. The QS regulation FDA 483 items will be compared to the steps of the flowcharts in the QSIT Handbook. The flowchart steps correspond to the key elements of the firm's Quality System that are to be evaluated when performing a QSIT inspection. The results of the reviews will be tabulated and assessed for each of the three Districts participating in the Study. The match of QS regulation FDA 483 items to the flowchart steps will indicate that the key elements of the Quality System were evaluated during the inspection as directed by the QSIT. Evaluation of key elements among districts correlates to a consistent approach to conducting inspections.* Overall responsibility for this activity: T. Wells (HFZ-332) and G. Layloff (HFR-SW450) *Note: Goal/Outcome O1B addresses consistency among investigators within the Study Districts.	
Acceptance criteria (if known)	Majority of the FDA 483 items correspond to the steps of the QSIT flowcharts.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**	This activity will provide a direct and objective measurement of whether the directives of QSIT regarding evaluation of key elements were followed. The following of the QSIT directives among districts correlates to a consistent approach to conducting inspections. This activity does not determine if consistency among districts has increased.	
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.	This pre-deployment activity will demonstrate if the QSIT directives regarding the evaluation of key elements are being followed consistently among districts.	

Rev.12/18/98

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
O1A	Increase consistency among districts for conducting comprehensive Quality System inspections of medical device manufacturers.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
2	Test	The comparison of FDA 483 items to the steps in the flowcharts in the QSIT Handbook.
Acceptance Criteria	Majority of the FDA 483 items correspond to the steps of the QSIT flowcharts.	
Summary of Results	The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. A total of 42 QSIT inspections were conducted during the Study. A total of 28 FDA 483s containing a total of 200 items were issued during those inspections. The FDA 483s were reviewed by HFZ-320 and the individual FDA 483 items were compared to the steps of the flowcharts in the QSIT Handbook. A tabulation of the results is attached. A total of 178 of the 200 FDA 483 items were found to match the QSIT Handbook flowchart steps. Of the remaining 22 items, 10 were directly linked to CAPA and PAPC flowchart steps. The remaining 12 items appear to be linked to PAPC flowchart steps.	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments	The frequency of subsystem deficiencies was not level across the Districts. For example, deficiencies in Management were cited at a rate of approx. 3/1 (i.e. 3 FDA 483 items per FDA 483 issued) in District 1, 0.4/1 in District 2, and 2/1 in District 3. The cause(s) of this aberration is unknown.	
Activity Champion(s)	Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332)	

Item # O1A (Activity 2)

FDA483 Review Results
(QS Regulation Deficiencies)

	CODE	1A1	1A2	1A3	1A4	1B1	1C1	1C3	1C4	1D1	1D2	1D3	1D4	2A1	2B1	2B2	2C4	2D2	2D3	2D4	3A1	3A4	3B1	3B2	3B3	3B4	3C2	3C3	3D3	TOTAL
MGMT	1				3		1			1				1								1	3		1		1			12
	2										2	1																	1	4
	3a																													0
	3b					1		1			2											1	2			1				8
	4a	1			1																		1				1	1		5
	4b																													0
	5	2				1		2		1	1	2		1													1	1		12
	6	2	1		1	1		2		2	2	1					1						1	1		1				16
DESIGN	1							1																						1
	2				1					1	1																			3
	3																													0
	4																													0
	5			1																										1
	6						1																			1				2
	7			1					1																					2
	8										2																			2
	9						1																							1
	10																													0
	11								1		1																			2
	12																				1									1
	13	1		1			2														2							1		7
	14		1												1									1	1					4
	15																													0

	CODE	1A1	1A2	1A3	1A4	1B1	1C1	1C3	1C4	1D1	1D2	1D3	1D4	2A1	2B1	2B2	2C4	2D2	2D3	2D4	3A1	3A4	3B1	3B2	3B3	3B4	3C2	3C3	3D3	TOTAL
CAPA	1	1			3		1			1				1		1										1		1	2	12
	2			2			1	2			1					2			1		1		1							11
	3																													0
	4																								1					1
	5						1																			1				2
	6							3			1					2			2		1									9
	7			1					1								1					1				3				7
	8		2					1																						3
	9	1						1							2															4
	10																				1									1
PAPC	1a																													0
	1b																													0
	2				1	2	1	1	4	1	1		2	1				1	2		3	1	1	3	1	1		1	1	29
	3a					1																								1
	3b	1						1		1											3		1	1						8
	4								1												1	1								3
	5																		1			1								2
	6																			1						1				2
Other			1[1]				4[1]			1[1]	1	5		1						1	2[1]	3			2[2]	1				22
Total		9	5	6	10	6	13	15	8	9	15	9	2	5	3	5	2	1	6	2	15	9	10	6	6	11	3	5	4	200

[1] Linkage between PAPC and D&R

[2] Linkage between CAPA and D&R

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
O1A (Activity 3)	Increase consistency among districts for conducting comprehensive Quality System inspections of medical device manufacturers.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	Coverage of the 4 major subsystems of QSIT as reported in the EIR.
Scope and nature of the process to be followed.[2]	The QSIT directs coverage of 4 major subsystems of the Quality System – Management Controls, Design Controls, Corrective and Preventive Action, and Production and Process Controls. During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct comprehensive medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections. Beginning the week of 1/11/99, the EIRs for the QSIT Study inspections will be reviewed to determine if the major subsystems were covered during the Study inspections. The results of the reviews will be tabulated and assessed for each of the three Districts participating in the Study. The match of EIR reported coverage to the 4 major subsystems will indicate that the subsystems were evaluated during the inspection as directed by the QSIT. Coverage of the 4 major subsystems among districts correlates to a consistent approach to conducting inspections*. Overall responsibility for this activity: T. Wells (HFZ-332) and G. Layloff (HFR-SW450) *Note: Goal/Outcome O1B addresses consistency among investigators within the Study Districts.	
Acceptance criteria (if known)	Majority of EIRs report coverage of the 4 major subsystems	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**	This activity will provide a direct and objective measurement of whether the directives of QSIT coverage of the 4 major subsystems were followed. Th following of the QSIT directives among districts correlates to a consistent approach to conducting inspections. This activity does not determine if consistency among districts has increased.	
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.	This pre-deployment activity will demonstrate if the QSIT directives regarding the coverage of the 4 major subsystems are being followed consistently among districts.	

Rev.12/18/98

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
O1A	Increase consistency among districts for conducting comprehensive Quality System inspections of medical device manufacturers.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
3	Test	Coverage of the 4 major subsystems of QSIT as reported in the EIR.
Acceptance Criteria	Majority of EIRs report coverage of the 4 major subsystems.	
Summary of Results	The QSIT Study directs coverage of 4 major subsystems of the Quality System. The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. A total of 42 QSIT inspections were conducted during the Study. The EIRs from 40 of those inspections were submitted for review by COB 3/10/99. The submitted EIRs were reviewed to determine if the 4 major subsystems were covered during the Study inspections. A tabulation of review results is attached. Of the 40 EIRs reviewed, 39 reported coverage of the 4 major subsystems. In one instance, coverage of Design Controls was not attempted because Design Controls had been assessed during a previous EI of 6/25-7/10/98 and found to be NAI.	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments	When objectionable conditions are observed based upon samples of records chosen using the sampling tables found within the QSIT Handbook, the Sampling Plans Instructions contained in the Handbook direct investigators to state in the EIR the Sampling Table and Row used to select their samples. The EIR review revealed that, in general, references to the Sampling Table and Row were not being made by the investigators. While not directly related to this particular activity, this issue is related to the Outcome O1 - Increase Consistency. Therefore, the Handbook has been revised to provide clearer instructions to the investigators regarding sampling and reporting. In addition, QSIT training materials are being designed to address this area.	
Activity Champion(s)	Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332)	

Item # O1A (Activity 3)

EIR review for reported coverage of the 4 major subsystems.

TABULATION of REVIEW RESULTS

Inspection Code	Yes	No	Comment	*
1A1	X			B
1A2	X			B
1A3	X			B
1A4			EIR not submitted by COB 3/10/99	B
1B1	X			B
1B2	X			B
1B3	X			B
1C1	X			A
1C2	X			A
1C3	X			A
1C4	X			A
1D1	X			C
1D2	X			C
1D3	X			C
1D4	X			C
2A1	X			A
2B1	X			C
2B2	X			C
2B3	X			C
2C1	X			C
2C2	X			C
2C3	X			C
2C4	X			C
2D1	X			B
2D2	X			B
2D3	X			B
2D4		X	Design controls NA1 during previous EI 6/25-7/10/98. Not covered during QSIT inspection.	B
3A1	X			C
3A2	X			C
3A3	X			C
3A4			EIR not submitted by COB 3/10/99.	C
3B1	X			C
3B2	X			C
3B3	X			C
3B4	X			C
3C1	X			B
3C2	X			B

Inspection Code	Yes	No	Comment	*
3C3	X			B
3C4	X			B
3D1	X			A
3D2	X			A
3D3	X			A
Total	39	1		

*Time in position as investigator, where A = 1-5 years, B = 6-10 years, and C >10 years

Note: When objectionable conditions are observed based upon samples chosen using the sampling tables found within the QSIT Handbook, the Sampling Plans Instructions contained in the Handbook direct investigators to state in the EIR the Sampling Table and Row used to select their samples. The EIR review revealed that, in general, references to the Sampling Table and Row were not being made by the investigators.

O1B

Increase Consistency Among Investigators

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
O1B (Activity 1)	Increase consistency among investigators for conducting comprehensive Quality System inspections of medical device manufacturers.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Analysis	Inspectional Objectives and narrative "linkages" described within the "QSIT Inspection handbook"
Scope and nature of the process to be followed.[2]	Compare the structure of a QSIT inspection described within the QSIT Inspection Handbook to that of the current comprehensive inspection technique described within DRAFT CP 7382.830 INSPECTION OF MEDICAL DEVICE MANUFACTURERS (May 1997) and the GUIDE TO INSPECTIONS OF MEDICAL DEVICE MANUFACTURERS (December 1997). Determine whether QSIT or the existing technique provides for a more defined, succinct and prescriptive methodology for the comprehensive inspection of medical device manufacturers. Providing a defined, succinct and prescriptive methodology to all FDA investigators will help ensure increased consistency in the inspection of medical device manufacturers by investigators. Overall responsibility for this activity: R. Ruff (HFR-CE350)	
Acceptance criteria (if known)	QSIT inspectional objectives and linkages provide for a more well defined, succinct and prescriptive methodology for the inspection of medical device manufacturers than the current technique.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**	This activity will provide direct and objective evidenc that the QSIT provides a more well defined, succinct and prescriptive methodology for the inspection of medical device manufacturers than the current technique. A potential weakness in this activity is tha some may debate whether a prescriptive technique is effective as a less prescriptive technique.	
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.	This pre-deployment activity will demonstrate that th QSIT technique is more well defined, succinct and prescriptive than the current technique via a direct comparison.	

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
01B	Increase consistency among investigators for conducting comprehensive Quality System inspections of medical device manufacturers.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
1	Analysis	Inspectional Objectives and narrative "linkages" described within the "QSIT Inspection Handbook"
Acceptance Criteria	QSIT inspectional objectives and linkages provide for a more well defined, succinct and prescriptive methodology for the inspection of medical device manufacturers than the current technique.	
Summary of Results	A comparison of the structure of a "QSIT" inspection described within the QSIT Inspection Handbook to that of the current comprehensive inspection technique ("T1997C") described within DRAFT CP 7382.830 INSPECTION OF MEDICAL DEVICE MANUFACTURERS (May 1997) and the GUIDE TO INSPECTIONS OF MEDICAL DEVICE MANUFACTURERS (December 1997) was conducted and analyzed. A table documenting the comparison appears as Attachment 1. Both techniques were described in terms of "Tasks". Each task was extracted from the appropriate inspectional reference and documented on Attachment 1. This activity attempted to extract only the tasks which an inspector is instructed to complete during a QSIT or T1997C inspection. Where either technique consisted of narrative discussions of regulatory requirements, no tasks were inferred. An analysis of the number of tasks required to accomplish (1) a comprehensive inspection of a non-sterile medical device manufacturer and (2) a comprehensive inspection of a sterile medical device manufacturer was conducted. This analysis appears as Attachment 2. For this activity the following assumptions were made (1) QS Regulation, MDR, Tracking and Corrections and Removals requirements were all applicable and (2) the manufacturer determined bioburden and used a contract irradiation sterilization service. In addition, Attachment 2 includes an analysis of the number of "References Providing Inspectional Instructions" that are required to be maintained and utilized during QSIT and T1997C inspections. Results include: 1. The comprehensive inspection of a non-sterile medical device manufacturer using QSIT requires 139 tasks and 1 reference. The comprehensive inspection of a non-sterile medical device manufacturer using T1997C requires 188 tasks and 3 references. 2. The comprehensive inspection of a sterile medical device manufacturer using QSIT requires 151 tasks and 1 reference. The comprehensive inspection of a sterile medical device manufacturer using T1997C requires 231 tasks and 4 references. 3. T1997C does not reflect contemporary inspectional requirements. E.g. (1) T1997C instructs the investigator to use the "Design Control Inspectional Strategy included in CP7382.830 Attachment F"and provides guidance from the "Transition" period. The referenced strategy has been obsolete and the transition period has been over since June of 1998. 4. QSIT provides a sampling methodology or a specific number when records are reviewed. T1997C provides sampling instructions only in CP7382.830A for field examination of sterile packages. In a number of tasks, T1997C requires inspection of "all" records. E.g. (1) "Review all records for the proper disposition of nonconforming products for assurance that use of nonconforming product has not resulted in the distribution of defective devices.", and (2) "Verify history records representing individual devices or lots of devices exist for all finished devices manufactured." This activity has demonstrated that QSIT will accomplish a comprehensive inspection (including Corrections and Removals) of a non-sterile medical device manufacturer in approximately 26% fewer tasks than T1997C (excluding Corrections and Removals) and utilizing approximately 67% fewer reference sources. This activity has demonstrated that QSIT will accomplish a comprehensive inspection (including Corrections and Removals) of a sterile medical device manufacturer in approximately 35% fewer tasks than T1997C (excluding Corrections and Removals) and utilizing 75% fewer reference sources. Through the use of sampling, QSIT provides "end points" for the review of records that are not prescribed in T1997C. Based upon the following facts (1) there are less tasks associated with QSIT (2) there is only one reference source associated with QSIT (also consider ease of maintenance) (3) the number of records reviewed is prescribed in QSIT and (4) QSIT contains contemporary inspectional requirements, QSIT has been demonstrated to provide a more well defined, succinct and prescriptive methodology for the comprehensive inspection of medical device manufacturers than T1997C.	
Conclusion	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments	This analysis was conducted prior to the conclusion of QSIT Field Test activities. The number of tasks required to conduct a QSIT inspection may change (increase or decrease) based upon the QSIT Field Test activities.	
Activity Champion(s)	Robert G. Ruff, CSO (HFR-CE350)	

QSIT Validation Worksheet Item O1B Activity 1 Comparison (Attachment 1, 10 pages)

QSIT		T1997C
1. Preannouncement Activities	Reference: QSIT Handbook	III A. 1. "When conducting all routine GMP inspections you are required to start the inspection with a review of: (1) complaints
Task 1 - Request and review copies of Quality Policy and High Level Quality System Procedures (Management Review Procedure, Quality Plan)		Task 1 - Determine if the firm has received complaints Task 2 - Review a sample of complaints (start from most current and work backwards to 24 months max., total depends on a number of factors e.g. skill of Invet. and storage medium) Task 3 - Ascertain what files contain complaints
2. Interview Management Representative	Reference: QSIT Handbook	Task 4 - Trend complaints (if not done by firm) Task 5 - Analyze to ID existing or potential causes of nonconforming product or quality problems Task 6 - Determine if adequate complaint investigation is performed Task 7 - Determine identity of individuals reviewing complaints Task 8 - Determine the qualifications of the individuals reviewing complaints Task 9 - Confirm all complaints are covered and reported Task 10 - If no complaints received, determine if provisions are in place Task 11 - If no complaints received, determine who will be responsible
Task 1 - Management Representative (or designee) interviewed prior to the inspection of each subsystem (min. 4 ea. interviews)		
3. Inspect Management Controls	Reference: QSIT Handbook	and MDR reports (see Attachment A, Section I (B)..." Note: "Attachment A" is a list of "Class I Devices exempt from most of the GMP Requirements By Classification Regulations" Attachment C contains guidance for determining manufacturer compliance with the MDR regulation.
Objective 1: Verify... Task 1 - Quality Policy Task 2 - Management Review Procedures Task 3 - Quality Audit Procedures Task 4 - Quality System Procedures and Instructions ...have been defined and documented. Objective 2: Verify... Task 1 - Quality Policy has been implemented Objective 3: Review established organizational structure to assure it includes provisions for... Task 1 - responsibilities Task 2 - authorities Task 3 - resources Objective 4: Confirm... Task 1 - Management Representative has been appointed Evaluate... Task 2 - Purview of the Management Representative Objective 5: Verify... Task 1 - Management Reviews are being conducted		Task 1 - Determine if there are written MDR procedures Task 2 - Determine if they are complete Task 3 - Determine if they are followed Task 4 - Determine if event files are maintained Task 5 - Determine if the file is easy to ID/access Task 6 - Determine if files contain the necessary reports and correspondence Task 7 - Determine if the files contain documentation regarding decisions not to file an MDR Task 8 - Document credentials of qualified medical staff making decision not to file Task 9 -Determine if the file contains copies of failure analyses, etc. Task 10 - Determine if MDR files contained in GMP files are readily IDable

Objective 6: Verify...
Task 1 - Quality Audits are conducted at sufficient frequency
Task 2 - Effectiveness of Audit
Task 3 - Independence of Auditor
Task 4 - Adequacy of Audit Procedure
Task 5 - Communication of findings to Upper Management
Task 6 - Corrective Actions implemented and Re-audits

4. Inspect Design Controls

Reference: QSIT Handbook

Objective 1: Select Design Project (if applicable)
Task 1 - Select a design project that meets 820.30(a)

Objective 2: Verify...
Task 1 - Design Control Procedures are defined and documented
Task 2 - DC Procedures address the specific requirements of 820.30

Objective 3: Review...
Task 1 - The Design and Development Plan

Objective 4: Confirm...
Task 1 - Design Inputs were established
Review...
Task 2 - Sources of input
Determine...
Task 3 - That relevant aspects were included

Objective 5: Verify...
Task 1 - Essential outputs are identified
Review...
Task 2 - Method for identifying essential outputs

Objective 6: Confirm...
Task 1 - Verification acceptance criteria established prior to activity
Task 2 - Validation acceptance criteria established prior to activity

Objective 7: Determine if...
Task 1 - Verification confirms output meets input (Sample Tables)

Objective 8: Confirm...
Task 1 - Validation data shows user needs and intended uses met

Task 11 - Examine files for computer generated "deficiency" letters
Task 12 - If deficiency letter received discuss and determine if problem resolved

III A. 1. (cont'd) "...(2) changes which the manufacturer has made in the design or manufacturing process,

Task 1 - Review design changes (see below "Design Control Report and Guidance")
Task 2 - Review manufacturing process changes
Task 3 - Determine if changes are validated and/or verified
Task 4 - Determine if there are a series of changes for the same problem
Task 5 - Document all design changes on DCIS Report

and (3) records of production lots which failed in-process or finished device testing.

Task 1 - Determine if the firm released lots that failed to meet specifications
Task 2 - Review DHR's or in-process control records of lots that have been rejected
Task 3 - Report and document shipment
Task 4 - Evaluate MRB rationales (if applicable)
Task 5 - Review re-work records
Task 6 - Determine if rework is adequate
Task 7 - Determine that rework does not affect S & E
Task 8 - Determine if sampling plans for inspection are acceptable
Task 9 - Determine if sampling plans for rework are acceptable
Task 10 - Analyze and trend nonconforming product records
Task 11 - Inspect data for repeat component failures
Task 12 - Determine if procedures to control nonconforming product are established
Task 13 - Determine if procedure is complete
Task 14 - Review all records of nonconforming product to ensure they didn't ship defective product.
Task 15 - Review concessions
Task 16 - Evaluate concessions for 510(k) applicability

"Any indications of problems that your review identifies will provide a focus for your inspection. If you do not find indications of problems after reviewing the above records, complete the inspection as directed in the Guide to Inspection of Medical Device Manufacturers and the Design Control Inspectional Strategy..."

Select devices for coverage based on above findings (plus service record review) or "....because of what they are made of or how they are made, have the highest potential for problems that could result in the design, manufacture and/or distribution of unsafe or unreliable devices."

Objective 9: Confirm...
Task 1 - Validation did not leave unresolved discrepancies

Objective 10: Confirm...
Task 1 - Software is validated (if device contains software)

Objective 11: Confirm...
Task 1 - Risk Analysis was completed

Objective 12: Determine if...
Task 1 - Validation was accomplished using initial production devices or their equivalents
Review...
Task 2 - Equivalency when equivalent devices are used

Objective 13: Confirm...
Task 1 - A pre-production change was controlled appropriately
Task 2 - A post-production change was controlled appropriately

Objective 14: Determine...
Task 1 - If design reviews were conducted
Confirm...
Task 2 - An individual without direct responsibility was included
Task 3 - Outstanding action items have or are being resolved

Objective 15: Determine if...
Task 1 - The design was correctly transferred
Compare...
Task 2 – The device master record against outputs (Sample Tables)

Servicing:

Task 1 - Determine if adequate system is in place to screen service and repair reports for complaints
Task 2 - Cross- reference service related complaints in complaint handling system
Task 3 - Review service reports for MDR events

Corrective and Preventive Actions:

Task 1 - Determine whether the firm has conducted any recalls or market withdrawals

III A. 6 "Confirm that all subject recalls conducted by the establishment since the last inspection have, in fact, been reported to the district office. Also review files to determine if all events filed by the establishment as Class III recalls have been properly classified..."

Task 2 - Determine if the firm has established CAPA procedures
Task 3 - Determine if the firm analyzes repair and service records for warranty failure trends
Task 4 - Review records of investigations to ID common failure trends
Task 5 - Compare these trends with corrective action documentation
Task 6 - Conduct "detailed" inspection of CAPA records
Task 7 - Review trending information performed by firm
Task 8 - Review corrective actions already implemented
Task 9 - Review service records (amount relates to same criteria as for complaints)
Task 10 - Determine if service reports were analyzed for existing or potential causes of nonconforming product or other quality problems
Task 11 - Review for trends by sorting "fields"

Process Validation:

Task 1 - Determine if the results of the process cannot be fully verified by subsequent inspection and test
Task 2 - Determine if processes are contributing to defective products
Task 3 - Review process validation to ID defect characteristics and expected rates
Task 4 - Review first and last article test results
Task 5 - If problems, question control parameters, environmental conditions, components etc.
Task 6 - Determine whether adequate prospective or retrospective validation was performed

5. Inspect CAPA	Reference: QSIT Handbook

Objective 1: Verify...
Task 1 - CAPA Procedures are defined and documented
Task 2 - CAPA Procedures address the specific requirements of 820.100

Objective 2: Determine if...(re: corrective action)
Task 1 - Appropriate sources of quality data have been identified
Confirm...
Task 2 - The data is being analyzed

Objective 3: Determine if...(re: preventive action)
Task 1 - Appropriate sources of quality data have been identified
Confirm...
Task 2 - The data is being analyzed

Objective 4: Verify that quality data is... (Sample Tables)
Task 1 - Entered
Task 2 - Complete
Task 3 - Accurate
Task 4 - Timely

Objective 5: Verify...
Task 1 - Appropriate statistical methods are employed
Task 2 - Non-statistical methods are employed
Determine if...
Task 3 - Results are compared across different data sources
Objective 6: Determine if... (Sample Tables)
Task 1 - Failure investigation procedures are followed
Task 2 - Investigation is commensurate with the significance and risk
Task 3 - Root cause identified
Verify...
Task 4 - Control for prevention of distribution of nonconforming product

Objective 7: Determine if... (Sample Tables)
Task 1 - Appropriate actions are taken

Objective 8: Determine if...
Task 1 - The action(s) were effective
Task 2 - The action(s) were verified or validated
Confirm...
Task 3 -The action(s) do not adversely affect the finished device

Components:

Task 1 - Determine if nonconforming devices are manufactured because of nonconforming components (review complaints, concessions, etc.)
Task 2 - Determine if appropriate statistical method is used for acceptance sampling
Task 3 - Review and evaluate test and/or screening of components
Task 4 - For JIT vendors, review audit procedure and schedule

Quality Audits:

Task 1 - Determine if written audit procedure exists
Task 2 - Determine frequency of audits
Task 3 - Interview an auditor (if possible)
Task 4 - Determine whether corrective action by upper management is being taken
Task 5 - Confirm re-audits of deficient matters are conducted when required

Design Controls:

Note: Although the DRAFT CP 7382830 and December 1997 Guide to Inspection of Medical Device Manufacturers refer to the Design Control Inspectional Strategy, for this comparison, I used the tasks described in the Design Control Report and Guidance which is contemporary.

Task 1 - Select a device subject to design controls
Task 2 - Determine whether the design project related to an original design or modification to an existing design
Task 3 - Determine at what stage in the design project, design controls were applied
Task 4 - Determine if Design and Development plan is complete
Task 5 - Determine whether the plan was reviewed, updated and approved
Task 6 - Review design input procedures
Task 7 - Confirm design input procedures are complete
Task 8 - Review process for resolving incomplete, ambiguous...requirements
Task 9 - Review how design input addresses user interface
Task 10 - Confirm design input is reviewed, approved and documented
Task 11 - Review design output procedures
Task 12 - Confirm design outputs expressed in terms that allow comparison to inputs
Task 13 - Review technique for identification of essential outputs
Task 14 - Confirm that design output is reviewed, approved and documented
Task 15 - Review design review procedures
Task 16 - Assure the procedures ensure reviews are comprehensive
Task 17 - Confirm manufacturer has IDed appropriate stages for review
Task 18 - Review documentation from at least one design review

Objective 9: Verify that... (Sampling Tables)
Task 1 - Corrective and preventive actions are documented
Task 2 - Corrective and preventive actions have been implemented

Objective 10: Determine if...
Task 1 - Information is properly disseminated to responsible individuals
Task 2 - Information is disseminated for management review

6. Inspect P&PC

Reference: QSIT Handbook

Objective 1: Select a process...
Task 1 - Select a process based on criteria

Objective 2: Review... (Sample Tables)
Task 1 - The procedures for the process selected
Task 2 - The control methods
Task 3 - The monitoring methods
Confirm...
Task 4 - Equipment is maintained
Task 5 - Test equipment is controlled
Task 6 - Test equipment is calibrated
Verify...
Task 7 - DHR's vs. DMR
Task 8 - Purchasing controls are employed
Task 9 - Receiving acceptance activities
Task 10 - In-process acceptance activities
Task 11 - Finished device acceptance activities
Task 12 - Environmental controls
Task 13 - Contamination controls
Task 14 - Statistical techniques

Objective 3: If problem with DHR's...
Determine if...
Task 1 - Nonconformance(s) were recognized
Task 2 - Nonconformance(s) handled appropriately
Task 3 - Quality data fed to CAPA
Review...
Task 4 - Equipment adjustment
Task 5 - Equipment calibration
Task 6 - Equipment maintenance
Task 19 - Confirm problems or action items were addressed
Task 20 - Review design verification procedures
Task 21 - Review verification methods and data
Task 22 - Review procedures for design validation
Task 23 - Confirm validation was accomplished per procedure
Task 24 - If "equivalent" devices used, review how "equivalency" was determined
Task 25 - Review clinical and non-clinical evaluations
Task 26 - Review software validation (where applicable)
Task 27 - Identify risk analysis tools and techniques
Task 28 - Confirm data demonstrates needs of user and intended use met
Task 29 - Review design transfer procedure
Task 30 - Confirm that design transfer procedures were followed
Task 31 - Compare significant elements of DMR to finished design outputs
Task 32 - Review design change procedures
Task 33 - Confirm changes were made according to procedure
Task 34 - Confirm procedure assures changes are validated or verified
Task 35 - Confirm there is written justification when verified but not validated
Task 36 - Confirm design changes are reviewed, approved and documented
Task 37 - Confirm changes were appropriately communicated
Task 38 - Confirm DHF contains necessary elements
Task 39 - Confirm the firm can identify each device in design family or group

PMA Devices

Task 1 - Determine if site is approved

Medical Device Tracking

Task 1 - Determine if device is a tracked device
Task 2 - Determine whether procedures exist
Task 3 – Determine adequacy of procedures

Follow-up to OAI Inspection: (if applicable)

Task 1 - Determine whether all previous FDA-483 observations were investigated
Task 2 - Determine implementation of all corrective actions re: previous FDA-483

Personnel:

Task 1 - Look for examples of potential training deficiencies
Task 2 - Verify firm has procedures for identifying training needs

Evaluate validation study...

Task 7 - Instruments calibrated
Task 8 - Instruments maintained
Task 9 - Confirm predetermined product specifications
Task 10 - Test sampling plans valid
Task 11 - Objective evidence spec.s met consistently
Task 12 - Tolerances challenged
Task 13 - Equipment properly installed
Task 14 - Equipment properly adjusted
Task 15 - Equipment properly maintained
Task 16 - Monitoring instruments calibrated
Task 17 - Monitoring instruments maintained
Task 18 - Changes properly challenged
Task 19 - Operators appropriately qualified

Objective 5: Confirm software is validated...
Review...

Task 1 - Software requirements document
Task 2 - Software validation protocol
Task 3 - Software validation activities
Task 4 - Software change controls
Task 5 - Software validation results

Objective 6: Verify... (Sample Tables)
Task 1 - Employees are aware of device defects
Task 2 - Employees conducting QC inspections aware of defects and errors
Task 3 - Review training records
Task 4 - Verify all personnel have been made aware of defects
Task 5 - Verify personnel involved with verification or validation are aware of defects, etc.

Document Controls:

Task 1 - Verify written procedures are signed and dated as approved
Task 2 - Verify DMR is signed and dated as approved
Task 3 - Verify DHR is signed and dated as approved
Task 4 - Assure all documents are available at point of use
Task 5 - Review document change records

Purchasing Controls:

Task 1 - Verify written procedures capture necessary requirements
Task 2 - Verify firm's evaluation of suppliers
Task 3 - Verify type and extent of control activities is defined based on evaluations
Task 4 - Verify that there are records of acceptable suppliers
Task 5 - Verify the firm has written requirements for purchased items and services

Identification and Traceability:

Task 1 - Compare DHR's with DMR to ensure appropriate components were used in each stage of manufacturing
Task 2 - Compare DHR's against incoming and in-process acceptance activities to ensure only "passed" product was used

Production and Process Controls:

Task 1 - Verify specifications and documented work instructions are provided for all processes in which variations could result in failure of the finished device to meet specifications
Task 2 - Verify specification and procedure changes are reviewed and approved using a formal process and procedure
Task 3 - Verify new specifications and procedures are reviewed and approved using a formal process and procedure
Task 4 - Determine if components or devices are reworked
Task 5 - Verify written rework procedures are provided
Task 6 - Determine if manufacturer has assessed effect of rework
Task 7 - Determine if this assessment is documented

7. Inspect Sterilization Process Controls Replaces P&PC if Sterilization is process selected for inspection	Reference: QSIT Handbook

Objective 1: Review...
Task 1 - Validation Study Summary and Approval
Or, assess complete validation study ...
Task 1 - Instruments calibrated
Task 2 - Instruments maintained
Task 3 - Confirm predetermined product specifications
Task 4 - Confirm predetermined package specifications
Task 5 - Test sampling plans valid
Task 6 - Objective evidence spec.s met consistently
Task 7 - Tolerances challenged
Task 8 - Equipment properly installed
Task 9 - Equipment properly adjusted
Task 10 - Equipment properly maintained
Task 11 - Monitoring instruments calibrated
Task 12 - Monitoring instruments maintained
Task 13 - Changes properly challenged
Task 14 - Operators appropriately qualified
Task 15 - Periodic assessments of process adequacy

Objective 2: Review...
Task 1 - The procedures for the sterilization process selected
Task 2 - The control methods
Task 3 - The monitoring methods
Confirm...
Task 4 - Equipment is maintained
Task 5 - Test equipment is controlled
Task 6 - Test equipment is calibrated
Verify...
Task 7 - DHR's vs. DMR
Task 8 - Purchasing controls are employed
Task 9 - Receiving acceptance activities
Task 10 - In-process acceptance activities
Task 11 - Finished device acceptance activities
Task 12 - Packaging integrity acceptance activities
Task 13 - Environmental controls
Task 14 - Contamination controls
Task 15 - Statistical techniques
Task 8 - Verify that there are documented inspections of environmental controls
Task 9 - Verify the washing and toilet facilities are clean and adequate
Task 10 - Verify clothing requirements and controls are adequate
Task 11 - Verify that contamination procedures exist
Task 12 - Verify that the contamination procedures are adhered to
Task 13 - Verify eating, drinking and smoking is limited to designated areas (if applicable)
Task 14 - Verify that sewage, trash etc. is handled appropriately
Task 15 - Verify personnel are clean, healthy, etc.
Task 16 - Verify personnel are excluded from affected operations when appropriate
Task 17 - Verify written procedures require employs to report health conditions
Task 18 - Verify there are written maintenance procedures and schedules
Task 19 - Verify there is written documentation of maintenance activities
Task 20 - Verify equipment inherent limitations are visibly posted
Task 21 - Verify periodic inspections are conducted of maintenance schedules
Task 22 - Verify that these inspections are per a written procedure
Task 23 - Verify manufacturing material is removed or limited
Task 24 - Verify there are written procedures for the control of man. material
Task 25 - Verify software of production equipment is validated
Task 26 - Verify software of quality system equipment is validated
Task 27 - Verify changes to software are validated and approved
Task 28 - Verify validation activities are documented
Task 29 - Verify inspection, measuring and test equipment is checked
Task 30 - Verify inspection, measuring and test equipment is calibrated
Task 31 - Verify inspection, measuring and test equipment is inspected
Task 32 - Verify inspection, measuring and test equipment is maintained
Task 33 - Verify these activities are according to written procedures
Task 34 - Verify these activities are documented
Task 35 - Verify the procedures include provisions for handling, preservation and storage
Task 36 - Verify Handling, preservation, etc. activities are documented
Task 37 - Verify written calibration procedures include specific limits, etc.
Task 38 - Review calibration records
Task 39 - Verify remedial actions are documented when limits are exceeded
Task 40 - Verify standards are traceable to nat'l or int'l standard
Task 41 - Verify calibration records are displayed on or near ea. piece of equipment
Task 42 - Verify calibration records include equip. ID, calib. dates, next calib. date

Objective 3: If problem with DHR's... Determine if...
Task 1 - Nonconformance(s) were recognized
Task 2 - Nonconformance(s) handled appropriately
Task 3 - Quality data fed to CAPA
Task 4 - Re-test is appropriate (if applicable)
Task 5 - Effects of re-sterilization are understood (if applicable)
Review...
Task 6 - Equipment adjustment
Task 7 - Equipment calibration
Task 8 - Equipment maintenance

Objective 4: Confirm software is validated...
Review...
Task 1 - Software requirements document
Task 2 - Software validation protocol
Task 3 - Software validation activities
Task 4 - Software change controls
Task 5 - Software validation results

Objective 5: Verify... (Sample Tables)
Task 1 - Employees are aware of device defects
Task 2 - Employees conducting QC inspections aware of defects and errors

Sterilization EIR Reporting Requirements:

Item 1 - ID all sterilization processes used by the firm
Item 2 - ID sterilization process covered
Item 3 - ID of standard used for process covered
Item 4 - Location of sterilization sites
Item 5 - Division of responsibilities for sterilization activities
Item 6 - SAL
Item 7 - Whether or not parametric release is used

Labeling and Packaging control:

Task 1 - Verify the firm has labeling operation control procedures
Task 2 - Verify the procedures are adequate
Task 3 - Verify packaging and shipping containers are adequate

Handling, Storage, Distribution and Installation

Task 1 - Review distribution records against final inspection and quarantine records
Task 2 - Review records of receipt and dispatch to confirm procedures are followed
Task 3 - Review service records to ensure service is not required immediately after installation

Records:

Task 1 - Encourage firm to mark records they deem to be confidential
Task 2 - Review DMR for completeness
Task 3 - Ensure there is a formal method for approving and changing the DMR
Task 4 - Verify there are DHR's for all finished devices
Task 5 - Verify DHR's contain evidence that labeling was examined prior to use

Pre-Approval Device Inspection (PMA, and Class III 510(k):

Task 1 - Verify accuracy of information submitted
Task 2 - Assess the firm's ability to meet the QS Reg.
Task 3 - Determine if changes were communicated to review staff

Sterile Devices:

Task 1 - Obtain records to document any deficiencies related to validation
Task 2 - Determine if firm is or may be manufacturing nonsterile devices (via review of release records, process records, bioburden records, product and packaging changes, etc.)
Task 3 - Review records of lots with positive sterility test results
Task 4 - Review records of lots with positive BI results
Task 5 - Review any re-sterilization records due to process failures
Task 6 - Verify re-sterilized lots were adequately reworked
Task 7 - Verify re-sterilized lots were adequately tested

CP 7382.830A contains a number of additional tasks to be accomplished for a sterile device. E.g. Attach. B requires approximately thirty-six additional tasks for the inspection of a manufacturer who uses an irradiation contract sterilizer

Inspect MDR, C&R and Tracking (Conducted during inspection of CAPA)	Reference: QSIT Handbook

MDR:

Objective 1: Verify...
Task 1 - Written MDR procedures address the requirements of 803.17

Objective 2: Verify... (Sample Tables)
Task 1 - MDR event files are prominently IDed
Task 2 - MDR event files are easy to access
Confirm...
Task 3 - MDR event files contain the necessary information

Objective 3: Confirm... (Sample Tables)
Task 1 - That the appropriate MDR information is identified
Task 2 - That the appropriate MDR information is reviewed
Task 3 - That the appropriate MDR information is documented
Task 4 - That the appropriate MDR information is filed

Objective 4: Confirm... (Sample Tables)
Task 1 - That the procedures are effective (review unreported event files)
Determine...
Task 2 - The firm's rationale for not filing MDR's for apparent MDR events

C&R:

Objective 1: Determine...
Task 1 - Whether the firm has implemented any corrections
Task 2 - Whether the firm has implemented any removals

Objective 2: Confirm... (Sample Tables)
Task 1 - Select and review files of reported C&R's
Task 2 - Select and review files of other CAPA's for C&R's

Objective 2: Verify... (Sample Tables)
Task 1 - Files of non-reportable C&R's are maintained
Task 2 - Files contain the necessary information
Task 3 - The files are retained for the appropriate amount of time

Confirm…
Task 4 - The files do not contain evidence of unreported recalls
Task 5 - Any claims for exemption
Verify…
Task 6 - If device was sold to another firm, files were transferred

Tracking:

Objective 1: Determine…
Task 1 - If the firm manufactures a tracked device
Task 2 - If yes, if the firm is aware of its tracking obligations
Confirm…
Task 3 - If the device was purchased form another firm, that the prior firm's tracking records (or equivalents) were obtained

Objective 2: Verify…
Task 1 - The firm has established a written tracking procedure
Task 2 - The procedure contains the necessary requirements
Task 3 - Information requested by FDA is provided as requested
Task 4 - Information requested by FDA is provided within timeframes

Objective 3: Confirm…
Task 1 - The firm has audited its tracking system
Task 2 - The audit procedures are complete

O1B Activity 1 Attachment 2 (1 page)

Number of Tasks and Number of References Required to Conduct (1) A Comprehensive Inspection of a Non-Sterile Medical Device Manufacturer and (2) A Comprehensive Inspection of a Sterile Medical Device Manufacturer

Regulatory Requirement	Number of Tasks Required to Provide Inspectional Coverage		Number of References Providing Inspectional Instructions		Comments
	QSIT	T1997C	QSIT	T1997C	
Quality System Regulation (non-sterile device)	110	171*	1	3**	*Does NOT include: confirmation of PMA site approval or PMA, Class III 510(k) tasks (4 ea.) **(1) DRAFT CP 7382.830, (2) Guide to Inspections of Medical Device Manufacturers (3) Design Control Report and Guidance
Quality System Regulation (sterile device***)	122	214*	1	4****	***Device man. determines bioburden, contract irradiation sterilization ****(1) DRAFT CP 7382.830 (2) Guide to Inspections of Medical Device Manufacturers (3) Design Control Report and Guidance (4) CP 7382.830A
Medical Device Reporting	10	12	1	2	
Medical Device Tracking	9	3	1	2	
Medical Device Corrections and Removals	10	2	1	0	
Total Number of Tasks (non-sterile device)	**139**	**188**			
Total number of references required			1	3**	
Total Number of tasks (sterile device*)**	**151**	**231**			
Total number of references required			1	4****	

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
O1B (Activity 2)	Increase consistency among investigators for conducting comprehensive Quality System inspections of medical device manufacturers.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	The comparison of FDA483 items to the steps in the flowcharts in the QSIT Handbook.
Scope and nature of the process to be followed.[2]	During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct comprehensive medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections. Beginning the week of 1/11/99, the FDA 483s for the QSIT Study inspections will be reviewed by C. Tylka, HFZ-320. The QS regulation FDA 483 items will be compared to the steps of the flowcharts in the QSIT Handbook. The flowchart steps correspond to the key elements of the firm's Quality System that are to be evaluated when performing a QSIT inspection. The results of the reviews will be tabulated and assessed for each investigator within each District participating in the Study. The match of QS regulation FDA483 items to the flowchart steps will indicate that the key elements of the Quality System were evaluated during the inspection as directed by the QSIT. Evaluation of key elements among investigators within each district correlates to a consistent approach to conducting inspections within districts*. Overall responsibility for this activity: T. Wells (HFZ-332) and G. Layloff (HFR-SW450) *Note: Goal/Outcome O1A addresses consistency among Districts.	
Acceptance criteria (if known)	Majority of the FDA483 items correspond to the steps of the QSIT flowcharts.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**	This activity will provide a direct and objective measurement of whether the directives of QSIT regarding evaluation of key elements were followed. The following of the QSIT directives among investigators within the Study Districts correlates to a consistent approach to conducting inspections. This activity does not determine if consistency among investigators has increased.	
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.	This pre-deployment activity will demonstrate if the QSIT directives regarding the evaluation of key elements are being followed consistently among investigators.	

Rev.12/18/98

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
O1B	Increase consistency among investigators for conducting comprehensive Quality System inspections of medical device manufacturers.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
2	Test	The comparison of FDA 483 items to the steps in the flowcharts in the QSIT Handbook.
Acceptance Criteria	Majority of the FDA 483 items correspond to the steps of the QSIT flowcharts.	
Summary of Results	The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. A total of 42 QSIT inspections were conducted during the Study. A total of 28 FDA 483s containing a total of 200 items were issued during those inspections. The FDA 483s were reviewed by HFZ-320 and the individual FDA 483 items were compared to the steps of the flowcharts in the QSIT Handbook. A tabulation of the results is attached. Key elements of the Quality System were evaluated among investigators within each district. A total of 178 of the 200 FDA 483 items were found to match the QSIT Handbook flowchart steps. Of the remaining 22 items, 10 were directly linked to CAPA and PAPC flowchart steps. The remaining 12 items appear to be linked to PAPC flowchart steps.	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments	As referenced in Item # O1A (Activity 2), the frequency of subsystem deficiencies was not level across the Districts. For example, deficiencies in Management were cited at a rate of approx. 3/1 (i.e. 3 FDA 483 items per FDA 483 issued) in District 1, 0.4/1 in District 2, and 2/1 in District 3. The cause(s) of this aberration is unknown. This aberration does not appear to exist among investigators within districts.	
Activity Champion(s)	Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332)	

Item # 01B (Activity 2)

FDA483 Review Results
(QS Regulation Deficiencies)

	CODE	1 A 1	1 A 2	1 A 3	1 A 4	1 B 1	1 C 1	1 C 3	1 C 4	1 D 1	1 D 2	1 D 3	1 D 4	2 A 1	2 B 1	2 B 2	2 C 4	2 D 2	2 D 3	2 D 4	3 A 1	3 A 4	3 B 1	3 B 2	3 B 3	3 B 4	3 C 2	3 C 3	3 D 3	TOTAL
MGMT	1				3		1			1				1								1	3		1		1			12
	2										2	1																	1	4
	3a																					1	2			1				0
	3b					1		1			2																			8
	4a	1			1																		1				1	1		5
	4b																													0
	5	2				1		2		1	1	2		1													1	1		12
	6	2	1		1	1		2		2	2	1					1						1	1		1				16
DESIGN	1							1																						1
	2				1					1	1																			3
	3																													0
	4																													0
	5			1																										1
	6						1																		1					2
	7			1					1																					2
	8										2																			2
	9						1																							1
	10																													0
	11								1		1																			2
	12																				1									1
	13	1		1			2														2						1			7
	14		1												1									1	1					4
	15																													0

	CODE	1A1	1A2	1A3	1A4	1B1	1C1	1C3	1C4	1D1	1D2	1D3	1D4	2A1	2B1	2B2	2C4	2D2	2D3	2D4	3A1	3A4	3B1	3B2	3B3	3B4	3C2	3C3	3D3	TOTAL
CAPA	1	1			3		1			1				1		1							1			1		1	2	12
	2			2			1	2			1					2			1		1		1							11
	3																													0
	4																								1					1
	5						1																			1				2
	6							3			1					2			2		1									9
	7			1					1								1					1				3				7
	8		2					1																						3
	9	1						1							2															4
	10																				1									1
PAPC	1a																													0
	1b																													0
	2				1	2	1	1	4	1	1		2	1				1	2		3	1	1	3.	1	1		1	1	29
	3a					1																								1
	3b	1						1		1											3		1	1						8
	4								1												1	1								3
	5																		1			1								2
	6																		.	1						1				2
Other			1[1]				4[1]			1[1]	1	5		1						1	2[1]	3			2[2]	1				22
Total		9	5	6	10	6	13	15	8	9	15	9	2	5	3	5	2	1	6	2	15	9	10	6	6	11	3	5	4	200

[1] Linkage between PAPC and D&R

[2] Linkage between CAPA and D&R

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
O1B (Activity 3)	Increase consistency among investigators for conducting comprehensive Quality System inspections of medical device manufacturers.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	Coverage of the 4 major subsystems of QSIT as reported in the EIR.
Scope and nature of the process to be followed.[2]	The QSIT directs coverage of 4 major subsystems of the Quality System – Management Controls, Design Controls, Corrective and Preventive Action, and Production and Process Controls. During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct comprehensive medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections. Beginning the week of 1/11/99, the EIRs for the QSIT Study inspections will be reviewed to determine if the major subsystems were covered during the Study inspections. The results of the reviews will be tabulated and assessed for each investigator within each District participating in the Study. The match of EIR reported coverage to the 4 major subsystems will indicate that the subsystems were evaluated during the inspection as directed by the QSIT. Coverage of the 4 major subsystems among investigators correlates to a consistent approach to conducting inspections*. Overall responsibility for this activity: T. Wells (HFZ-332) and G. Layloff (HFR-SW450) *Note: Goal/Outcome O1A addresses consistency among Districts.	
Acceptance criteria (if known)	Majority of EIRs report coverage of the 4 major subsystems	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**	This activity will provide a direct and objective measurement of whether the directives of QSIT coverage of the 4 major subsystems were followed. T following of the QSIT directives among investigators correlates to a consistent approach to conducting inspections. This activity does not determine if consistency among investigators has increased.	
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.	This pre-deployment activity will demonstrate if the QSIT directives regarding the coverage of the 4 majc subsystems are being followed consistently among investigators.	

Rev.12/18/98

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
O1B	Increase consistency among investigators for conducting comprehensive Quality System inspections of medical device manufacturers.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
3	Test	Coverage of the 4 major subsystems of QSIT as reported in the EIR.
Acceptance Criteria	Majority of EIRs report coverage of the 4 major subsystems.	
Summary of Results	The QSIT Study directs coverage of 4 major subsystems of the Quality System. The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. A total of 42 QSIT inspections were conducted during the Study. The EIRs from 40 of those inspections were submitted for review by COB 3/10/99. The submitted EIRs were reviewed to determine if the 4 major subsystems were covered during the Study inspections. A tabulation of review results is attached. 14 of 14 EIRs from District #1 reported coverage of the 4 major subsystems. 11 of 12 EIRs from District #2 reported coverage of the 4 major subsystems.* 14 of 14 EIRs from District #3 reported coverage of the 4 major subsystems. *In one instance, coverage of Design Controls was not attempted because Design Controls had been assessed during a previous EI of 6/25-7/10/98 and found to be NAI.	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments	When objectionable conditions are observed based upon samples of records chosen using the sampling tables found within the QSIT Handbook, the Sampling Plans Instructions contained in the Handbook direct investigators to state in the EIR the Sampling Table and Row used to select their samples. The EIR review revealed that, in general, references to the Sampling Table and Row were not being made by the investigators. While not directly related to this particular activity, this issue is related to the Outcome O1 - Increase Consistency. Therefore, the Handbook has been revised to provide clearer instructions to the investigators regarding sampling and reporting. In addition, QSIT training materials are being designed to address this area.	
Activity Champion(s)	Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332)	

Item # O1B (Activity 3)

EIR review for reported coverage of the 4 major subsystems.

TABULATION of REVIEW RESULTS

Inspection Code	Yes	No	Comment	*
1A1	X			B
1A2	X			B
1A3	X			B
1A4			EIR not submitted by COB 3/10/99	B
1B1	X			B
1B2	X			B
1B3	X			B
1C1	X			A
1C2	X			A
1C3	X			A
1C4	X			A
1D1	X			C
1D2	X			C
1D3	X			C
1D4	X			C
2A1	X			A
2B1	X			C
2B2	X			C
2B3	X			C
2C1	X			C
2C2	X			C
2C3	X			C
2C4	X			C
2D1	X			B
2D2	X			B
2D3	X			B
2D4		X	Design controls NAI during previous EI 6/25-7/10/98. Not covered during QSIT inspection.	B
3A1	X			C
3A2	X			C
3A3	X			C
3A4			EIR not submitted by COB 3/10/99.	C
3B1	X			C
3B2	X			C
3B3	X			C
3B4	X			C
3C1	X			B
3C2	X			B

Inspection Code	Yes	No	Comment	*
3C3	X			B
3C4	X			B
3D1	X			A
3D2	X			A
3D3	X			A
Total	39	1		

*Time in position as investigator, where A = 1-5 years, B = 6-10 years, and C >10 years

Note: When objectionable conditions are observed based upon samples chosen using the sampling tables found within the QSIT Handbook, the Sampling Plans Instructions contained in the Handbook direct investigators to state in the EIR the Sampling Table and Row used to select their samples. The EIR review revealed that, in general, references to the Sampling Table and Row were not being made by the investigators.

O2

Increase Compliance

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
O2 (Activity 1)	Increase compliance of medical device manufacturers with the Quality Systen regulation.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	Industry responses to a question on a Customer Satisfaction Survey
Scope and nature of the process to be followed.[2]	During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections. The most responsible person at each of the inspected firms who was directly involved in the inspection will b mailed an OMB approved Customer Satisfaction Survey. They will be invited to voluntarily provide their views on the QSIT by completing and returning the survey form. The survey form will contain the question, "Do you think that use of the QSIT will result in improved compliance of the medical device industry with the Quality System regulation? Yes [ ] No [ ] Please explain. " Responses will be tabulated and analyzed. Overall responsibility for this activity: G. Layloff (HFR-SW450) and T. Wells (HFZ-332)	
Acceptance criteria (if known)	The majority of survey responses affirm that use of the QSIT would result in an improvement of compliance of the medical device industry with the Quality System regulation.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**		This activity provides a direct but subjective measurement of the impact of QSIT on the outside "world".
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.		This pre-deployment activity allows firms (stakeholders) to express their views concerning the effect of QSIT on the improvement of compliance.

Rev.12/18/98

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
O2	Increase compliance of medical device manufacturers with the Quality System regulation.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
1	Test	Industry responses to a question on a Customer Satisfaction Survey
Acceptance Criteria	The majority of survey responses affirm that the use of the QSIT would result in an improvement of compliance of the medical device industry with the Quality System regulation.	
Summary of Results	The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. A total of 42 inspections were conducted during the Study. Subsequent to the conclusion of the inspection, the most responsible person at each of the 42 inspected firms who was directly involved in the inspection was mailed an OMB approved Customer Satisfaction Survey. They were invited to voluntarily provide their views on the QSIT by completing and returning the survey form. The survey form contained the question: "Do you think that use of the QSIT will result in improved compliance of the medical device industry with the Quality System regulation? Yes [ ] No [ ] Please explain." A total of 19 (45%) industry responses were received. A tabulation of individual responses is attached. Responses to the question were as follows: Yes 12 (63%) No 3 (16%) Other 4 (21%) *(Specific yes or no answers were not provided.)*	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments		
Activity Champion(s)	Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332)	

Item # O2 (Activity 1)

QUALITY SYSTEM INSPECTION TECHNIQUE (QSIT) CUSTOMER SATISFACTION SURVEY question:

Do you think that use of the QSIT will result in improved compliance of the medical device industry with the Quality System regulation? Yes [ ] No [ ] Please explain.

TABULATION of RESPONSES

Form	Yes	No	Other	Comment
1	X			As stated in #5 above our employees work toward fulfilling the intent of the Quality System Regulation not just the "letter of the law."
2	X			This method leads to quality improvement. The hunt for an error is negative.
3	X			In the areas inspected – unless other areas are also randomly inspected there are always those who will take advantage.
4	X			For the same reason as question #5 above. *(Note- The response to #5 was, " It will strengthen the similarity with ISO 9001/EN 46001 requirements because of the four key elements addressed by QSIT".)*
5	X			It is easier to understand and follow.
6			No response	Not sure
7		X		I believe the industry is focused on the Quality System Regulation. If I answer yes it would imply we currently do not.
8	X			Our experience with QSIT did help our compliance with Quality System Regulation.
9			No response	No opinion
10	X			The better the understanding of the requirements, the better the compliance with the QSR.
11	X			Areas of deficiency will be immediately highlighted.
12		X		Compliance is a philosophical attitude of individual companies that exists independently of the type of audits performed.
13		X		FDA is uncomfortable reviewing systems since 1. They are not familiar & 2. Spends less time on verification/validation. I think the traditional FDA inspection method (w/in reason) is good. Sometimes a good balance bet. Compliance to system are required and need to be re-enforced.
14			No response	Probably – If companies have no intention of complying it won't make a difference, but for those companies that are interested it will make it easier.
15	X			It is easier to understand exactly what is required.
16			No response	I do not know the answer to this question.
17	X			The emphasis on Design Control should help companies used to "GMP" to comply with the design history requirements. The emphasis on CAPA should encourage companies to show more proactive preventive actions.
18	X			It will become obvious to the inspector the level of commitment to or understanding of the Quality System Regulation by the manufacturer early during the inspection. I believe most companies are committed to and understand the Quality System Regulation.
19	X			This system inspection approach supports the changes in the Quality System regulation. Inspecting top down rather then bottom up follows the new management responsibility section of the regulation. Looking at companies from the system approach will help FDA understand how the entire Quality Systems work or do not work. In the long run this approach will be beneficial to FDA and industry.
TOTAL	12	3	4	

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
O2 (Activity 2)	Increase compliance of medical device manufacturers with the Quality System regulation.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	Industry responses to a question on a Customer Satisfaction Survey
Scope and nature of the process to be followed.[2]	*The Blair House Papers*, issued 1/97 by President Clinton and Vice President Gore, discuss the relationship between regulators and the regulated community. Per those papers (pp. 15,16), "...Not everyone is going to play by the rules. But experience shows that most businesses and communities do want to comply and will, if they can figure out what it is they're supposed to do. Agencies are proving that, working with new partners, agreeing on the goals, allowing room for innovation, and providing all the help possible to those that want to comply. And because regulatory time is no longer being wasted on the good guys, agencies can better focus their attention on the few cheaters." The QSIT was developed with input from the regulated industry and public. The technique, as contained in the publicly available QSIT Handbook and implemented during an inspection, is one way of increasing the medical device industry's knowledge and understanding of the requirements of the QS regulation. This increase in knowledge and understanding will lead to an increase in compliance. During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections. The most responsible person at each of the inspected firms who was directly involved in the inspection will be mailed an OMB approved Customer Satisfaction Survey. They will be invited to voluntarily provide their views on the QSIT by completing and returning the survey form. The survey form will contain the question, "Do you think that use of the QSIT will increase the medical device industry's knowledge and understanding of the requirements of the Quality System Regulation? Yes [ ] No [ ] Please explain. " Responses will be tabulated and analyzed Overall responsibility for this activity: G. Layloff (HFR-SW450) and T. Wells (HFZ-332)	
Acceptance criteria (if known)	The majority of survey responses affirm that use of the QSIT would result in an increase in the medical device industry's knowledge and understanding of the requirements of the Quality System Regulation.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**		This activity provides an indirect measurement of the impact of QSIT on the outside "world".
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.		This pre-deployment activity allows firms (stakeholders) to express their views concerning the affect of QSIT on the increase in the medical device industry's knowledge and understanding of the requirements of the QS Regulation. An increase in knowledge and understanding correlates with an increase in compliance.

Rev.12/18/98

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
O2	Increase compliance of medical device manufacturers with the Quality System regulation.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
2	Test	Industry responses to a question on a Customer Satisfaction Survey
Acceptance Criteria	The majority of survey responses affirm that the use of the QSIT would result in an increase in the medical device industry's knowledge and understanding of the requirements of the Quality System Regulation.	
Summary of Results	The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. A total of 42 inspections were conducted during the Study. Subsequent to the conclusion of the inspection, the most responsible person at each of the 42 inspected firms who was directly involved in the inspection was mailed an OMB approved Customer Satisfaction Survey. They were invited to voluntarily provide their views on the QSIT by completing and returning the survey form. The survey form contained the question: "Do you think that use of the QSIT will increase the medical device industry's knowledge and understanding of the requirements of the Quality System Regulation? Yes [ ] No [ ] Please explain." A total of 19 (45%) industry responses were received. A tabulation of individual responses is attached. Responses to the question were as follows: Yes 18 (95%) No 0 (0%) Other 1 (5%) *(A specific yes or no answer was not provided.)*	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments		
Activity Champion(s)	Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332)	

Rev. 2/12/99

Item # O2 (Activity 2)

QUALITY SYSTEM INSPECTION TECHNIQUE (QSIT) CUSTOMER SATISFACTION SURVEY question:

Do you think that use of the QSIT will increase the medical device industry's knowledge and understanding of the requirements of the Quality System Regulation? Yes [ ] No [ ] Please explain.

TABULATION of RESPONSES

Form	Yes	No	Other	Comment
1	X			By focusing on our Quality System and being able to demonstrate effectiveness our employees are better educated as to what an FDA inspection will encompass.
2	X			The industry will be judged by many people but using similar criteria.
3	X			Inspection of areas designated is more thorough thus allowing greater understanding of the requirement.
4	X			It will strengthen the similarity with ISO 9001/EN 46001 requirements because of the four key elements addressed by QSIT.
5	X			It provides a more straight forward approach and less guessing on both parties.
6			No response	Not sure.
7	X			Standardized format for investigation and focus on the quality system as a system versus separate elements.
8	X			Our QSIT audit was very helpful for us.
9	X			Provides a lot of information that is easily understood and logical in its approach.
10	X			The QSIT Inspection Handbook provides insight into FDA's expectations with respect to the QSR, and therefore gives the industry detailed guidance.
11	X			A QSIT very quickly identifies the specific requirements of the QSR.
12	X			Auditors have the opportunity to learn in advance of their appearance at the site areas the company needs help and instruction/correction.
13	X			Yes since our systems do meet QSR as well as ISO requirements. Better for business.
14	X			It is an extremely focused approach that makes possible a corresponding manufacturer preparation focus.
15	X			It helps to make the auditing experience less mysterious.
16	X			The use of QSIT allows industry an insight into what the FDA is looking for from industry.
17	X			The emphasis on management review and design control will help "GMP" based companies transition to the QSR.
18	X			I'm not sure if it will increase the understanding of the requirements of the Quality System Regulation, but it will increase the understanding of the FDA's expectations or interpretations of the Quality System Regulation.
19	X			The QSIT Inspection Handbook and regular onsite visits should increase industry understanding of FDA expectations and the Quality System Regulation.
TOTAL	18	0	1	

O3

Improve Product Quality

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
O3 (Activity 1)	Improve the quality of medical devices	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	Industry responses to a question on a Customer Satisfaction Survey
Scope and nature of the process to be followed.[2]	During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections. The most responsible person at each of the inspected firms who was directly involved in the inspection will b mailed an OMB approved Customer Satisfaction Survey. They will be invited to voluntarily provide their views on the QSIT by completing and returning the survey form. The survey form will contain the question, "Do you think that use of the QSIT will result in an improvement of the quality of medical devices produced by the medical device industry? Yes [ ] No [ ] Please explain. " Responses will be tabulated and analyzed. Overall responsibility for this activity: G. Layloff (HFR-SW450) and T. Wells (HFZ-332)	
Acceptance criteria (if known)	The majority of survey responses affirm that use of the QSIT would result in an improvement of the quality o medical devices produced by the medical device industry.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**	This activity provides a direct but subjective measurement of the impact of QSIT on the outside "world".	
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.	This pre-deployment activity allows firms (stakeholders) to express their views concerning the effect of QSIT on the improvement of product quality.	

Rev.12/18/98

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
O3	Improve the quality of medical devices.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
1	Test	Industry responses to a question on a Customer Satisfaction Survey
Acceptance Criteria	The majority of survey responses affirm that the use of the QSIT would result in an improvement of the quality of medical devices produced by the medical device industry.	
Summary of Results	The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. A total of 42 inspections were conducted during the Study. Subsequent to the conclusion of the inspection, the most responsible person at each of the 42 inspected firms who was directly involved in the inspection was mailed an OMB approved Customer Satisfaction Survey. They were invited to voluntarily provide their views on the QSIT by completing and returning the survey form. The survey form contained the question: "Do you think that use of the QSIT will result in an improvement of the quality of medical devices produced by the medical device industry? Yes [ ] No [ ] Please explain." A total of 19 (45%) industry responses were received. A tabulation of individual responses is attached. Responses to the question were as follows: Yes 12 (63%) No 6 (32%) Other 1 (5%) *(A specific yes or no answer was not provided.)*	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments		
Activity Champion(s)	Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332)	

Rev. 2/12/99

Item # O3 (Activity 1)

QUALITY SYSTEM INSPECTION TECHNIQUE (QSIT) CUSTOMER SATISFACTION SURVEY question:

Do you think that use of the QSIT will result in an improvement of the quality of medical devices produced by the medical device industry? Yes [ ] No [ ] Please explain.

TABULATION of RESPONSES

Form	Yes	No	Other	Comment
1	X			Design Controls and effective corrective and preventive action have made a significant improvement in our facility.
2	X			Constantly improving Quality Systems yield improved products.
3	X			The areas currently targeted provide a very good look at what drives and controls quality of manufacture and service.
4	X			For the same reason as question #5 above. *(Note – The response to #5 was, "It will strengthen the similarity with ISO 9001/EN 46001 requirements because of the four key elements addressed by QSIT".)*
5		X		I still feel some companies may not follow/or care to follow the guidelines as close and adequately as needed.
6	X			Because of the design focus it should help. The greatest manufacturing in the world can" make up for faulty designs.
7		X		See answer on question #6. *(Note – The response to #6 was, "I believe the industry is focused on the Quality Systems Regulation. If I answer yes it would imply we currently do not".)* I think questions ^ & 7 are leading and not valuable as part of the QSIT approach overall.
8	X			Our quality's improvement was partly helped by QSIT.
9			No response	Do not feel qualified to give an opinion.
10	X			Focus on the Quality System subsystems and improvement in those should lead to improved quality, much more reliably than the 'bottom up' approach to correcting defects.
11	X			It specifically forces firms to define and document specific aspects of product develop. & process controls.
12	X			More efficient and directed audits should result in corrected deficiencies at audited sites resulting in improved systems and products.
13	X			As long as good systems are in place.
14		X		Don't believe it will have an impact. Companies either have a quality process, or they don't.
15		X		I know in my firm – our product is already high quality.
16	X			I do not think the QSIT will directly effect the quality of products. The approach to harmonization, however, will allow for consistency between inspectors.
17		X		Companies strive to produce the highest quality products and to meet the regulatory requirements regardless of the method used to audit them.
18		X		I don't believe that the inspection technique will have any affect on the quality of medical devices, but rather the improvement of the quality of medical devices will come from manufacturers implementing ISO 9001 and the quality system regulation.
19	X			I think this approach is a good thorough review of the quality systems. If industry is in compliance with the Quality system regulation it should ensure high quality medical devices. It is also my understanding that this method should decrease inspection time giving inspectors the opportunity to inspect more Device Firms. Timely inspection of all medical manufacturers will help ensure industry compliance and subsequently high quality devices.
TOTAL	12	6	1	

O4

Improve Review Efficiency

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
O4 (Activity 1)	Improve the efficiency of the enforcement action review process.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	Timeliness and quality of EIRs
Scope and nature of the process to be followed.[2]	A. QSIT trained Compliance officers, one each from DEN-DO, LOS-DO and MIN-DO, who participated in the QSIT Study, will be asked to complete and provide comments to the attached survey. Survey to issue by 1/29/99 Survey target completion date 2/12/99 Analysis to follow B. The replies to question #6 of the Compliance Officer QSIT Evaluation Form, that is being used during th QSIT Study, will be tabulated. Overall responsibility for this activity: S. Niedelman (HFZ-330)	
Acceptance criteria (if known)	An improvement in efficiency of regulatory action processing	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**	This activity adequately assesses the work accomplished to date. It is limited by the size and scop of the number of firms in the pilot and the limited number of trained compliance officers involved.	
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.	It summarily represents the experience of the inspectional and compliance personnel who have been included in the QSIT pilot.	

Rev.12/18/98

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
O4	Improve the efficiency of the enforcement action review process.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
1	Test	Timeliness and quality of EIRs
Acceptance Criteria	An improvement in efficiency of regulatory action processing.	
Summary of Results	A. Worksheet Results attached. B. Compilation of Question 6 from QSIT Evaluation form attached.	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments	Additional comments are included in each attachment.	
Activity Champion(s)	Steven Niedelman	

Quality System Inspection Technique (QSIT) Pilot

Compliance Officer Evaluation Form

1. Did the QSIT approach generally result in an EIR which was better organized and easier to review and evaluate?

   5 4 3 2 1 0
   (strongly agree) (do not agree)

2. Did the QSIT approach result in an EIR of generally higher quality?

   5 4 3 2 1 0

3. Did the QSIT approach result in more thorough documentation of violations?

   5 4 3 2 1 0

4. Did QSIT facilitate the preparation of regulatory action recommendations?

   5 4 3 2 1 0

5. Did QSIT affect the time needed to review the EIR?

   5 3 2 1 0
   (much quicker) (much longer) (none)

6. Did QSIT affect the time needed to prepare a regulatory recommendation?

   5 4 3 2 1 0
   (much quicker) (much longer) (N/A)

7. If QSIT had an affect on the quality of a regulatory action (or recommendation), that affect can best be described as:

   5 4 3 2 1 0
   (very positive) (negative) (none)

Please include any comments on your experience with QSIT and its effect on the review and preparation of regulatory actions or recommendations, or any other comments that you may have on QSIT below:

_____

_____

_____

_____

_____

_____

Quality System Inspection Technique (QSIT) Pilot

Attachment A. **Results of Compliance Officers Survey Form**

Footnote: Due to the small number of replies, it would not be accurate to "average the responses" to several questions, for some were not applicable, and averaging the results would negatively bias the outcome (because the numerical value "0" – represents not applicable!) The replies to each of these questions are described below.

Question 4. Actual replies were: 5(1), 2(2), and NA (3);
Question 6. Actual replies were: 5(1), 3(2), and 0(3);
Question 7. Actual replies were: 4(1), 3(3), and 0(3)

Comments:

(1) "I really liked the QSIT process because I didn't get extraneous information. As in all things, a lot depends on CSO technique – some are still way too wordy, some were too skimpy and had to be rewritten."

(2) "QSIT aids in the review for regulatory action. I didn't see much gain in preparation of the regulatory action itself. The organization of the subsystems in the EIR facilitated review."

(3) "QSIT assisted in moving to the justification for proceeding with the desired action. The handbook provided sufficient reassurance that all salient points were covered by regulation."

Quality System Inspection Technique (QSIT) Pilot

Attachment B. Tabulation of Question 6 – Compliance Officer Evaluation Form

Question 6. Did the investigator's focus on key areas help make your review easier?

Total number of forms submitted: 41 (15(1), 12(2) and 14(3))
Number of forms used for accounting: 39 (1, no reply (3); (1, both "Yes" and "No" checked off)
Tabulation of Responses: Yes: 37 (94.9%)
No: 2 (5.1%)

Comments:

District 1

- "Focused on system"
- "Helped concentrate on system"
- "Focused on violative areas that were significant"
- "Made it clear it was NAI"
- "Although it was pretty clear it was NAI"
- "Much easier"
- "As far as 483- focused on problems in validation, following procedures, complaints"
- "483 was focused on key areas."

District 2

- "Used subsystem headings on 483 and EIR – made review easier and Part V easy to apply"
- "There were no individual headings made under which each key area was reported. Having them would have expedited review."
- "Would be nice to make reporting structure uniform (require headings for each subsystem in EIR) to speed review."

District 3

- "Most definitely! Eliminates a lot of irrelevant materials. Traditionally I would look at Discussion with Management, Objectionable Conditions and Supporting Documentation to make decision."
- "Still a tendency to use essential elements of proof to formulate decision"
- "Especially in management controls"

Note: Numbers appearing in parentheses refer to the study number assigned to the reporting district.

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
O4 (Activity 2)	Improve the efficiency of the enforcement action review process.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	Responses by Compliance Officers to a multi-part question on an Evaluation Form
Scope and nature of the process to be followed.[2]	During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections. Each QSIT Study EI documentation is to be reviewed by QSIT trained compliance officers. There will be one compliance officer from each of the Study districts. The compliance officers will classify each EIR using QSIT Study draft Compliance Program 7382.830 Part V guidance. The compliance officers will complete an Evaluation Form for each of their reviews. They will be asked to provide their views on the QSIT Part V, and also on QSIT aspects which were designed to make the enforcement action review process more efficient. The effect of QSIT tools (Handbook – Objectives, purpose/importance statements, narratives, flowcharts, sampling tables) on the review process for inspections classified OAI using the QSIT Part V will be determined by the following multi-part Evaluation Form question: "Were the QSIT tools (Handbook – Objectives, purpose/importance statements, narratives, flowcharts, sampling tables) useful during your review? Yes __No __ If yes, which tools were most useful and how wer they helpful?" Responses will be tabulated and analyzed. Overall responsibility for this activity: G. Layloff (HFR-SW450) and T. Wells (HFZ-332)	
Acceptance criteria (if known)	The majority of responses affirm that the QSIT tools were useful during reviews of inspections classified OA using the QSIT Part V.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**	This activity provides a direct and objective measurement of whether the QSIT tools were useful during the review process. It provides an indirect measurement of the effect on the efficiency of the process.	
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.	This pre-deployment activity allows compliance offic (internal stakeholders) to express their views concerning the effect of QSIT on the performance of their duties.	

Rev.12/18/98

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
O4	Improve the efficiency of the enforcement action review process.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
2	Test	Responses by Compliance Officers to a multi-part question on an Evaluation Form
Acceptance Criteria	The majority of responses affirm that the QSIT tools were useful during reviews of inspections classified OAI using the QSIT Part V.	
Summary of Results	The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. QSIT Study EI documentation was reviewed by QSIT trained compliance officers (one from each of the Study Districts). The compliance officers classified the EIRs using QSIT Study draft Compliance Program 7382.830 Part V guidance. The compliance officers completed Evaluation Forms for their reviews. They provided their views on the QSIT Part V, and also on QSIT aspects which were designed to make the enforcement action review process more efficient. The effect of QSIT tools (Handbook – Objectives, purpose/importance statements, narratives, flowcharts, sampling tables) on the review process for inspections classified OAI using the QSIT Part V was determined by the following multi-part Evaluation Form question: "Were the QSIT tools (Handbook – Objectives, purpose/importance statements, narratives, flowcharts, sampling tables) useful during your review? Yes __ No __ If yes, which tools were most useful and how were they helpful?" A total of 42 QSIT inspections were conducted during the Study. A Compliance Officer QSIT Evaluation Form was submitted for 41 of those inspections. Of those 41 inspections, 9 were classified OAI by the QSIT compliance officers using the QSIT Part V. A tabulation of individual responses is attached. Responses to the question were as follows: Yes 5 (56 %) No 3 (33 %) Other 1 (11 %) *(1-No response)*	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments		
Activity Champion(s)	Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332)	

Item # O4 (Activity 2)

COMPLIANCE OFFICER QSIT EVALUATION FORM question:

Were the QSIT tools (Handbook – Objectives, purpose/importance statements, narratives, flowcharts, sampling plans) useful during your review? Yes __ NO __
If yes, which tools were most useful and how were they helpful?

TABULATION of RESPONSES
(Inspections Classified OAI Using the QSIT Part V)

Inspection Code	Yes	No	Other	Tools Most Useful and How They Were Helpful
1A1	X			Handbook
1A4	X			Book
1C3		X		
1C4	X			Book – helped me focus
1D1		X		
1D2	X			Narratives
1D3	X			Handbook narratives
2D3		X		
3B4			No response	
Total	5	3	1	

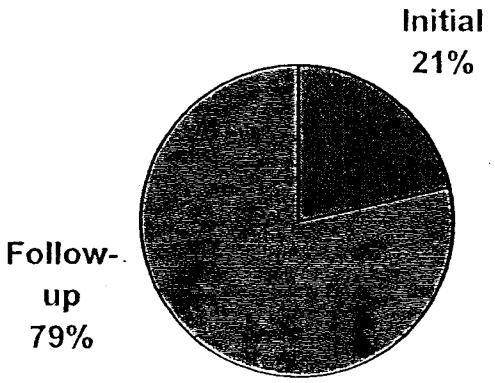
QSIT

Study

QSIT STUDY INSPECTIONS

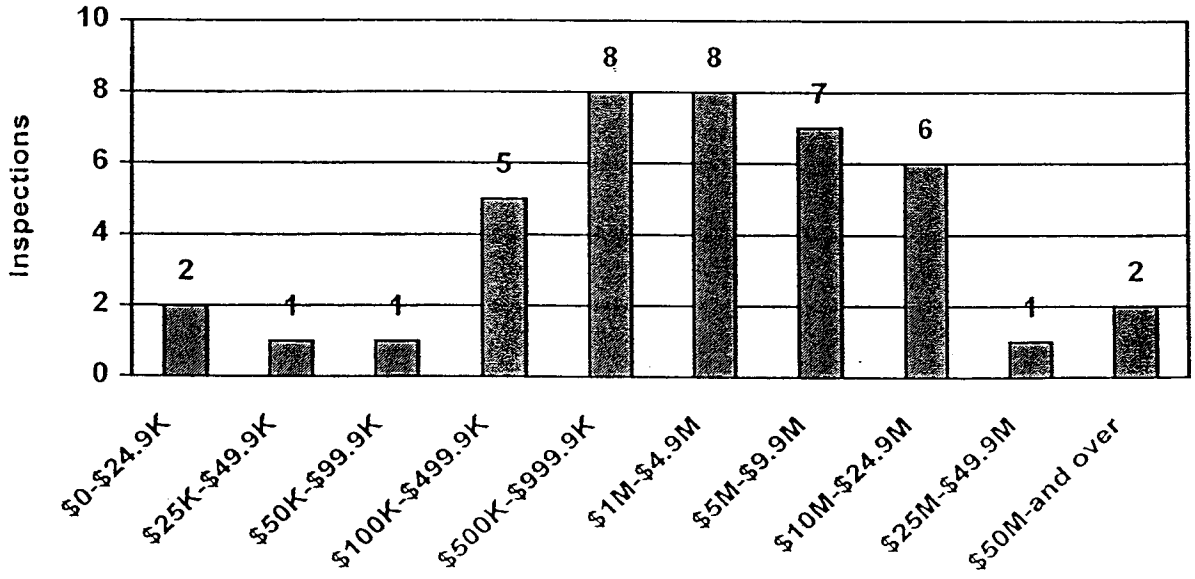
The QSIT Study was conducted 10/1/98 through 2/19/99. During the Study period 12 QSIT trained investigators, 4 each from DEN-DO, LOS-DO, and MIN-DO, conducted medical device Quality System inspections using the QSIT. A total of 42 inspections were conducted during the Study.

Of the 42 inspections, 9 were initial inspections of the firm's operations. The remaining 33 were follow-ups to a previous inspection.



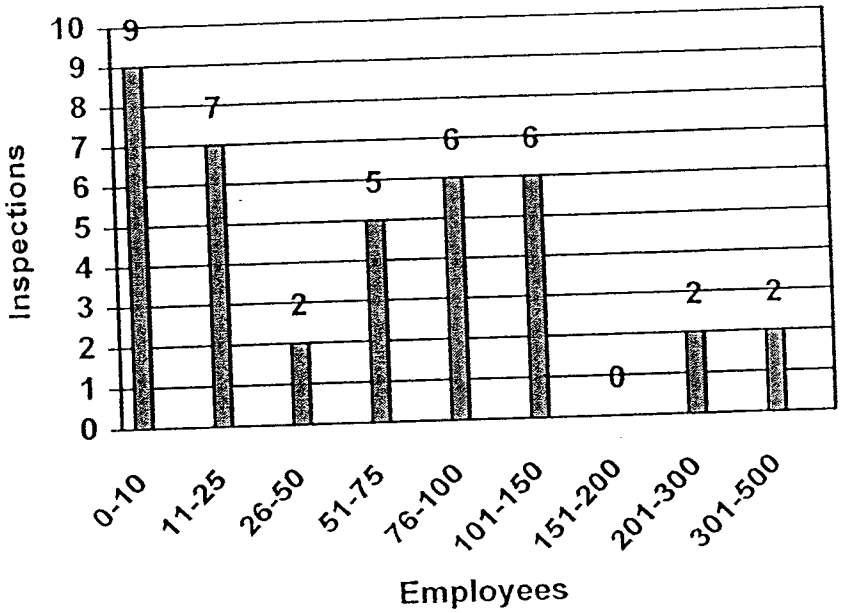
Types of Inspections

The annual dollar volumes as reported for 41 of the 42 inspected firms are as follows:

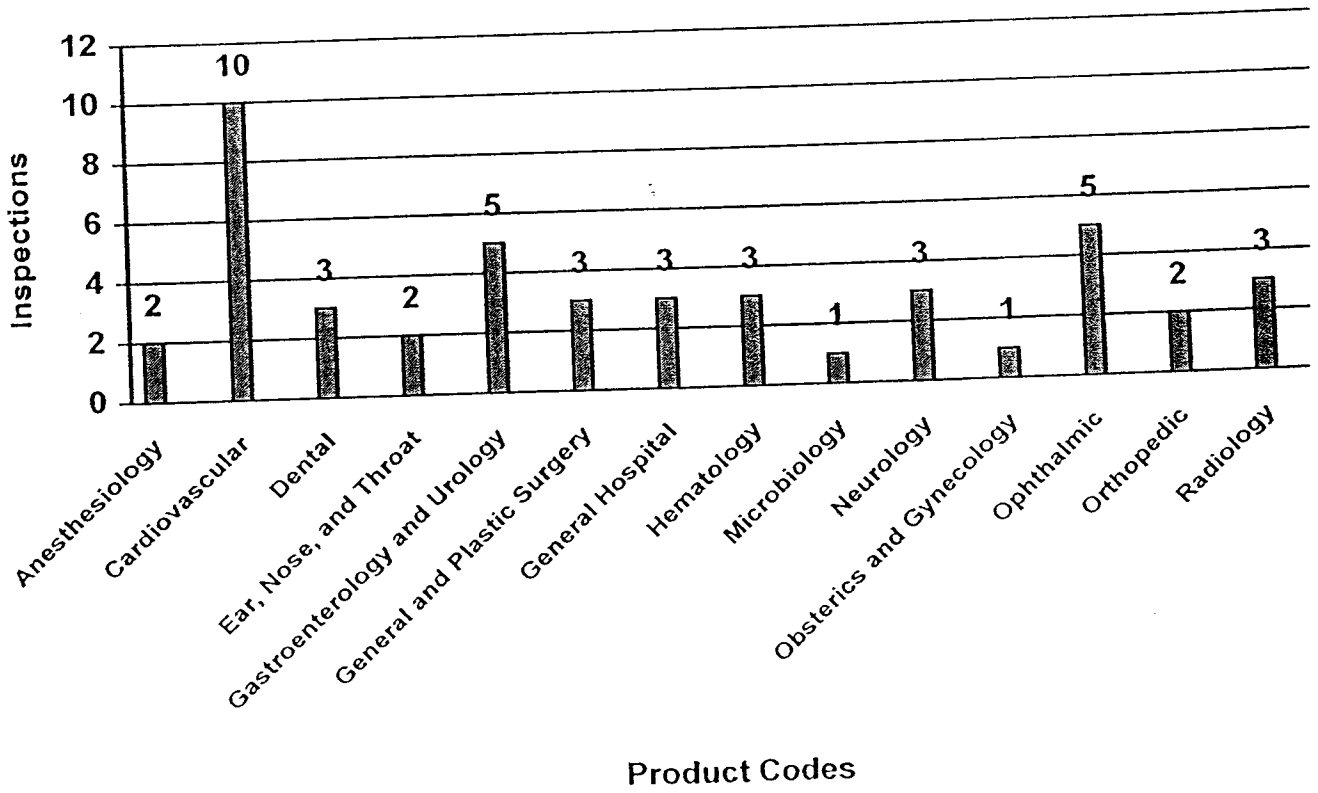


Annual Dollar Volumes

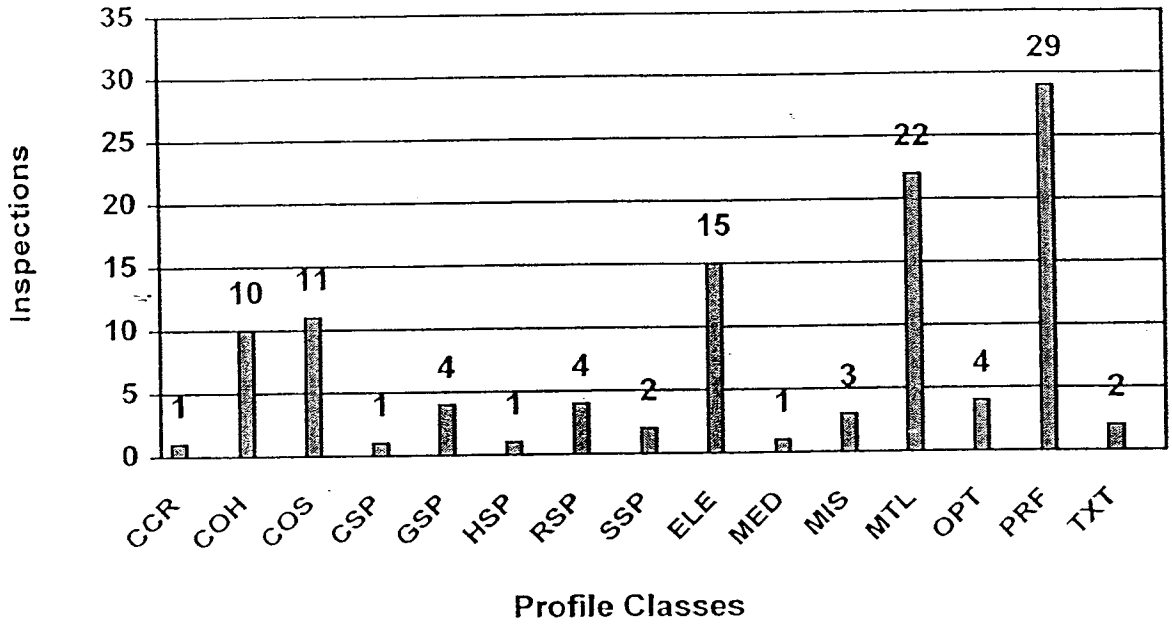
The approximate numbers of employees as reported for 39 of the 42 firms are shown below.



The product codes associated with those 42 inspections are shown below. *Note - For some inspections more then one product code was covered.*



The profile classes covered during those 42 inspections are as follows:



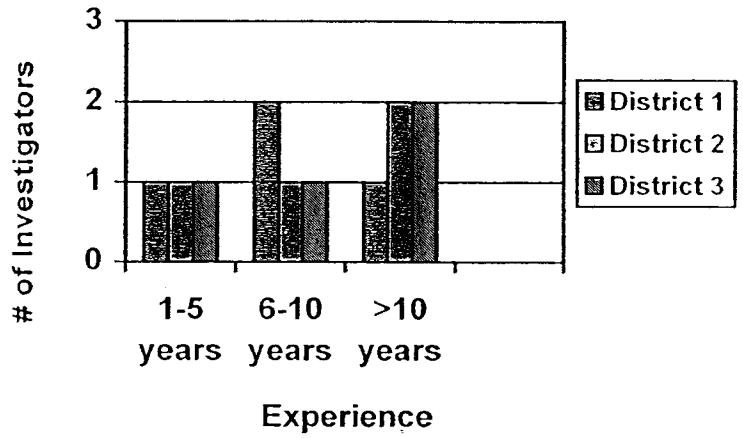
PROFILE CLASS CODES AND DEFINITIONS

CCR	Clinical Chemistry Reagents
COH	Computer Hardware
COS	Computer Software
CSP	Chemical Sterilization
GSP	Gas Sterilization
HSP	Dry Heat Sterilization
RSP	Radiation Sterilization
SSP	Steam Sterilization
ELE	Electrical Assembly
MED	Media
MIS	Not Elsewhere Classified
MTL	Metals Fabrication and Assembly
OPT	Optics Fabrication and Assembly
PRF	Plastic or Rubber Fabrication and Assembly
TXT	Textile Fabrication and Assembly

The following attached Forms were developed to collect and document the Study data associated with various validation activities:

1. QSIT Review (FDA 481(a), (c) and EIR) (Rev. 1/11/99)
2. QSIT FDA 483 Focus Review (Rev. 1/12/99)
3. INVESTIGATOR QSIT EVALUATION FORM (Rev. 9/30/98)
4. COMPLIANCE OFFICER QSIT EVALUATION FORM (Rev. 9/30/98)
5. Cover letter for QUALITY SYSTEM INSPECTION TECHNIQUE (QSIT) CUSTOMER SATISFACTION SURVEY
6. QUALITY SYSTEM INSPECTION TECHNIQUE (QSIT) CUSTOMER SATISFACTION SURVEY

The experience levels of the investigators performing the 42 QSIT Study inspections are shown below:



QSIT Review
(FDA 481(A), (C), and EIR)

District: DEN LOS MIN

Firm Name: _____

EI TYPE: INITIAL FOLLOW-UP EST TYPE: _____ EST SIZE: _____

PAC	PROCESS CODE	HOURS	PRODUCT	INSP CONC	DIST CONC

FDA 483 ISSUED: YES NO

PROFILE CLASS(es): _____ _____ _____ _____ _____ _____ _____

QSIT EIR ELEMENTS:

Design Project Covered: _____

Data Sources reviewed during evaluation of the CAPA subsystem: _____

_____

Process(es) covered: _____

COMMENTS: _____

_____

_____

Reviewer: _____ Date: _____

QSIT FDA 483 Focus Review

District: DEN LOS MIN

Firm Name: _____

FDA 483 observations were identified from the following subsystems and correspond to the following steps in the flowcharts in the QSIT Handbook:

Management:	1	2	3a	3b	4a	4b	5	6		
Design Ctrls:	1	2	3	4	5	6	7	8	9	10
	11	12	13	14	15					
CAPA:	1	2	3	4	5	6	7	8	9	10
P&PC:	1a	1b	2	3a	3b	4	5	6		

Other subsystems (identify cite) –

Doc/Records & Ch. Ctrls:

Facilities & Equip. Ctrls:

Material Ctrls:

Comments:

Reviewer: _____ Date: _____

INVESTIGATOR QSIT EVALUATION FORM

Firm Name _____ Inspection Date(s)_____
CFN _____

Approximate number of employees in firm _____

SUBSYSTEMS COVERED		APPROXIMATE TIME IN-PLANT
Management Controls	_____	_____
Design Controls	_____	_____
CAPA	_____	_____
PAPC *	_____	_____

*(Number of processes covered _____)

1. Was the inspection pre-announced? Yes _____ No _____
   If yes, were records voluntarily provided by the firm prior to the initiation of the inspection? Yes _____No_____
   If yes, were the records reviewed? Yes _____ No _____
   If yes, how much time was expended to review those records? _____
   Did this review increase the efficiency of the inspection? Yes _____ No _____
   Comments _____
   _____

2. Were the QSIT tools (Handbook - Objectives, purpose/importance statements, narratives, flowcharts, sampling plans) useful during this inspection? Yes _____ No _____
   If yes, which tools were most useful and how were they helpful? _____
   _____
   _____

3. Did use of the QSIT result in a more focused inspection? Yes _____ No _____
   Comments _____
   _____

4. Did use of the QSIT result in a more efficient inspection? Yes _____ No _____
   Comments _____
   _____

5. Other Comments: _____
   _____

Investigator: _____ Date: _____

Please submit this completed form to: Tim Wells, QSIT Team Leader, FDA CDRH HFZ-332, 2098 Gaither Rd., Rockville, MD 20850 .

(Rev date 9/30/98)

COMPLIANCE OFFICER QSIT EVALUATION FORM

Firm Name _____ Inspection Date (s) _____
CFN _____

BY USING THE QSIT STUDY PART V:

1. What classification would you make? _____

2. If classified OAI, which QSIT Study Part V requirements were met?
   A _____ B _____ C _____ D _____ E _____

3. Did the QSIT Study Part V help you in making your decision? Yes _____ No _____
   Comments _____
   _____

4. Did the QSIT Study Part V make your decision process more complicated? Yes____No____
   Comments_____
   _____

5. Did you find the QSIT Study Part V too structured? Yes _____ No _____
   If yes, explain._____
   _____

6. Did the investigator's focus on key areas help make your review easier? Yes _____ No _____
   Comments _____
   _____

7. Were the QSIT tools (Handbook - Objectives, purpose/importance statements, narratives, flowcharts, sampling tables) useful during your review? Yes _____ No _____
   If yes, which tools were most useful and how were they helpful? _____
   _____
   _____

8. Other Comments: _____
   _____

Compliance Officer: _____ Date: _____

Please submit this completed form and a copy of the EIR, FDA483, if issued, CGCS with PDS, and WL, if issued, to: Tim Wells, QSIT Team Leader, FDA CDRH HFZ-332, 2098 Gaither Rd., Rockville, MD 20850

(Rev date 9/30/98)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

The Center for Devices and Radiological Health is currently engaged in a reengineering effort to improve our Quality System/Good Manufacturing Practice inspection program. The goals of this reengineering effort are to conduct more focused and efficient inspections using an inspection technique called the QSIT (Quality System Inspection Technique) that is closer aligned with that inspection technique used by the international community. We believe these goals would benefit both the FDA and the industry.

The QSIT is being studied in several FDA Districts. The inspection of your facility, on the above dates, was conducted using this technique.

As part of our evaluation of that study, we would like your views on the QSIT. We are requesting that you provide those views by completing the enclosed survey form. Participation in this survey is voluntary. However, we do hope you will respond because we believe your views will provide valuable input into our reengineering effort.

Please submit the completed survey form by mail or fax to: Ms. Georgia Layloff, QSIT Team, FDA, 12 Sunnen Drive, Suite 122, St. Louis, MO 63143, FAX 314-645-2969, Phone 314-645-1167, ext. 121, email glayloff@ora.fda.gov.

If you have any questions, please contact Georgia Layloff or myself.

Thank you in advance for your assistance.

Sincerely yours,

Timothy Wells
QSIT Team Leader
Center for Devices and Radiological Health
301-594-4616, ext. 126

Enclosure: As stated

QUALITY SYSTEM INSPECTION TECHNIQUE (QSIT)
CUSTOMER SATISFACTION SURVEY

Please provide the following information:

1. Did your company receive advance notification of the inspection? Yes [ ] No [ ]
   If yes, were copies of records voluntarily provided to the investigator by your firm prior to the initiation of the inspection? Yes [ ] No [ ]
   If yes, which records were voluntarily provided? _____
   _____
   Did providing such records facilitate the inspection process? Yes [ ] No [ ]
   Please explain. _____
   _____
   _____

2. Did the QSIT focus on the key elements of your quality system? Yes [ ] No [ ]
   If yes, how did this focus prove beneficial to your firm? Please give examples.
   _____
   _____
   _____

3. Did use of the QSIT result in a more efficient inspection by FDA? Yes [ ] No [ ]
   If yes, how did this efficiency prove beneficial to your firm? Please give examples.
   _____
   _____
   _____

4. We designed QSIT to be closer to the Global Harmonization Guideline for Auditing Quality Systems. Did you find the QSIT approach similar to that used by auditing organizations utilized by your firm (i.e. Notified Bodies, third party assessors, internal auditing groups etc.)? Yes [ ] No [ ] No Opinion or Experience with this subject [ ]
   If yes, was this useful to your firm? Yes [ ] No [ ]
   Explain and provide examples of the similarities and usefulness. _____
   _____
   _____
   _____

5. Do you think that use of the QSIT will increase the medical device industry's knowledge and understanding of the requirements of the Quality System Regulation? Yes [ ] No [ ]
   Please explain. _____
   _____
   _____

6. Do you think that use of the QSIT will result in improved compliance of the medical device industry with the Quality System regulation? Yes [ ] No [ ]
   Please explain. _____
   _____
   _____

7. Do you think that use of the QSIT will result in an improvement of the quality of medical devices produced by the medical device industry? Yes [ ] No [ ]
   Please explain. _____

8. Do you think that use of the QSIT will increase FDA's effectiveness in protecting and promoting the public health? Yes [ ] No [ ]
   Please explain. _____

9. How would you improve the QSIT?

10. Comments _____

Optional Items: Please note, the following information is not required to participate in the survey. The information may be used in the event we have follow-up questions.

Contact Name: _____
Firm Name: _____
Address: _____

Telephone Number: _____ *Fax Number:* _____
email Address: _____

Thank you for completing this survey. Your responses are very important to us. They will be used to assist in improving our efforts.

Please send this completed form by mail or fax to: Georgia Layloff, QSIT Team, FDA, 12 Sunnen Drive, Suite 122, St. Louis, MO 63143, fax (314) 645-2969.